

**FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR THE DISTRICT
HEALTH SERVICES**

by

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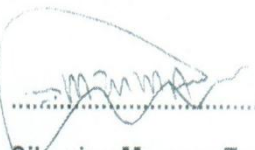
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DECEMBER 2016

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DECLARATION

I declare that **FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR THE DISTRICT HEALTH SERVICES** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.



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ABSTRACT

The purpose of this study was to develop a framework for provision of essential medicines for the district health services. A qualitative descriptive, exploratory and contextual action research design was followed. The data collection was conducted through site visits and semi structured interviews targeting the responsible pharmacists who were purposively selected on the basis of their expert knowledge and experiences from the eight of the nine provinces of the Republic of South Africa which is a developing country with limited resources for provision of healthcare services.

The study found that there was no standardised framework for provision of essential medicines for the District Health Services. Based on the site visits and action research findings a proposed Framework covering the selection, procurement, warehousing, distribution and management support components for provision of essential medicines for district health services was developed and subjected to national pharmaceutical experts and district health services managers review and critique which is finally presented, after taking into consideration the experts inputs as a proposed framework emanating from the study. The proposed framework will contribute towards improving the provisioning and availability of essential medicines within the district health services.

Keywords

Essential medicines; district health service; pharmaceutical services; medicine supply management; primary health care; nurses; framework.

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Dedication

I dedicate this thesis to young professional nurses equipped with managerial qualifications and work experience striving for health services management transformation for better health outcomes.

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LIST OF ABBREVIATIONS

GPP	Good Pharmacy Practice
MSH	Management Sciences for Health
NDOH	National Department of Health
NDP	National Drug Policy
PHC	Primary Health Care
PTC	Pharmaceutical and Therapeutic Committee
SAPC	South African Pharmacy Council
WHO	World Health Organization

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Pharmaceutical purchases (medicines) are the key cost driver for the health care system second only to the compensation of employees for the health budget (Management Science for Health [MSH] 2012:18.3). As a result, when the medicines are not available, the control and treatment of diseases is negatively affected resulting in the premature deaths and morbidity of the citizens. Medicines Sans Frontiers (MSF) (2013:13) reported that lack of access to medicines has complex underlying causes ranging from health programme implementation to medicine supply system.

A study conducted on pharmaceutical management of tuberculosis in seven of our nine provinces found that the availability of ARV and TB medication was at less than 95 % in five of the provinces namely the Free State, Eastern Cape, Gauteng, Limpopo, and Mpumalanga. The factors contributing to this low availability especially in primary health clinic settings included poor stock control and management in nurse-led primary health clinics, and a lack of pharmacist's assistants to take charge of drug supply management. Further a lack of electronic stock management systems also played a role in poor medicine availability as manual stock cards were found not to be updated at most facilities (Pure Health Consulting 2012:97).

Western Cape and North West had above 95% availability for essential medicines. The factors that contributed to the better access and availability included electronic stock management, maintenance of the 3 month buffer stock, close monitoring and weekly reporting on stock availability, active contract management, and interaction with the suppliers over quantification, shortages and forecasting of needs, involvement of all role-players in medicine stock management including finance, programme managers and pharmacists and adjustment of issuing quantities during limited stock period to ensure that all patients receive medication whilst waiting for the replenishment stock (Pure Health Consulting 2012:129).

In terms of policy guidelines, in South Africa the provision of medicines is guided by the National Drug Policy (NDP) whose objective is to ensure consistent availability of essential drugs (medicine) to all South African citizens (NDOH 1996:3). The essential medicines are those medicines required in order to treat the majority of diseases that affect the people, these medicines satisfy the priority health care needs of the population (WHO 2016). However, in practice there have been several challenges regarding medicine supply in South Africa, with various provinces reporting medicine stock outs to the extent that the inability to provide the required quantity and quality of medicines was identified as a key challenge facing the South African Government (Stock Out 2016:13). The challenge of medicine availability and access was confirmed by the Civic Organisation called Stop Stock Out Report that revealed that medicine stock out is a national crisis affecting all the nine provinces in particular for the HIV and TB medicines, with rural provinces being the worst affected at 54% stock out rate and also suffering major stock out for the vaccines at 35% in November 2013 (MSF 2013:7-12). The prevalent shortage of medicines requires that new approaches and models should be explored to ensure that medicines are accessible and affordable to the citizens of the country.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

In South Africa provision of medicines is governed by the Medicine and related Substance Act of 1965 as amended. The procurement of essential medicines for the public sector is done through the national tender system with provinces buying for the facilities falling within their areas of governance. South Africa has ten medical depots with Eastern Cape having two medical depots, independently run by the nine provinces with an objective to ensure consistent supply of the essential medicines.

The medical depots are responsible for coordination the procurement, distribution of the essential medicines including antiretroviral, tuberculosis, vaccines and chronic medicines and medical consumables namely gloves, syringes, injections and intravenous lines to the health facilities. Within these depots there are different procedures and no standard model utilised in the procurement and distribution of medicines across the country. Provinces including Eastern Cape and Northern Cape procure for all the facilities within their provinces whereas Western Cape province procure primarily for the district health

services as the larger hospitals are said to be well enabled to manage medicine and consumables supply utilising their own resources.

The South African government in 2009 realised the importance of medicine and medical supplies as an integral part of the platform for provision of quality health care services to an extent that medicine and medical consumables availability has been listed as one of the six priorities listed for the South African Department of Health (NDOH 2009a:1). The escalation to six priority list of these essential health commodities was adopted in order to improve the health profile of all South Africans. Further improving medicine supply and management have been identified as key action point in the South African Health Programme of Action. The Ten Point Plan of the South African National Department of Health places the emphasis on the review of drug policies which may lead to the improvement of medicine availability by means of improved procurement of medicines and the possible establishment of a state owned pharmaceutical industry (NDOH 2009b:5).

1.2.1 The source of the research problem

Only 14 percent of the South African health facilities achieved an acceptable level for the availability of (essential) medicines and supplies in the baseline health facilities audit conducted (Matsoso, Fryatt & Andrews 2015:98).

1.2.2 Background to the research problem

Prior to the effect of South Africa's democratic government dispensation in 1994, medicine policies were also in line with the fragmented provision of the health services model. This resulted in differentiated access and varied availability of medicines due to lack of standardised essential medicine lists. In 1996 the National Drug Policy (NDP) was developed and approved by the new government in line with WHO standard requirements of member countries developing and implementing national medicine policies. The primary objective for the NDP was that of ensuring the availability of essential medicines (medication) to all South African citizens. The NDP is supported by Standard Treatment Guidelines and the Essential Medicine List for each level of care to realise the provision of affordable essential medicines (South Africa 1996:3).

The government is expected to ensure availability of generic essential medicine through implementation of incentives that favour generic medicines and their production in the country (South Africa 1996:10).

Post 1994, in South Africa the major platform through which citizens' access basic health services and medicines became the primary health care centres which are located within the district health services. The provision of medicines in the primary health care context has been free for all citizens since 1994 in an attempt to promote healthy living and improve life expectancy of the population (South Africa 1996:1). Although the medicine policies are in place, medicine availability has not been at acceptable levels. During May 2010 South Africa experienced a shortage of over 80 medicines in the public health sector which included, amongst others, influenza vaccinations, medication for hypertension and tuberculosis. The severity of this shortage varied from province to province, as well as from hospital to hospital within the provinces, depending on the leadership abilities and skills levels of management (Health 24 2010).

The Public Service Commission results of the 2010 citizen survey also indicated that there were instances where citizens visited service delivery points and returned without receiving what they needed. Of the patient (10,5%) who participated in the survey were told to come the following day for their treatment, due to lack of sufficient stock of medicine or that it was time for staff to knock off for the day (Public Service Commission 2011:41). As the challenges with the health services provision, including medicine availability, continued to surface the need to strengthen District Health Services to become well-functioning was also identified as a core principle of primary health care re-engineering processes (Gray, Vawda & Jack 2011:23). The re-engineering process, it is believed, will contribute towards the efficiency of district health services in the rendering of required essential services and will ensure that health programmes are available. This will include the provision of medicines, as well as treatment and care to the population in the areas where they live. The South African Department of Health formally recognised that medicine availability is cardinal in the provision of quality health care services to the extent that medicine availability has been regarded as one of the six Ministerial priorities required for compliance in all public health facilities (NDOH 2011a:16).

In further developments over the years the South African Government has also regarded Health as one of 12 key outcomes to be prioritised during the 2009-2014 government

term of office towards ensuring a better life for all South Africans and the achievement of the millennium development goals during the period 2010-2015 (GCIS 2010). In order to improve the health profile of all South Africans improved medicine supply and management have been identified as key factors in the South African Health Programme of Action. However, the negative media coverage on the non-availability and stock out of medicines ensured the public health services a poor reputation as service users did not receive the expected medications as they visited health facilities (Thom & Langa 2010:7).

In 2011 the Ministry of Health commissioned a baseline audit for all public health facilities based on these standards. The purpose was to assess the current state of health services as well as the degree of compliance with standards. The results showed that the majority of health facilities did not comply with medicine availability standards due to stock out of essential medicines (Gray et al 2011:62). In 2012 the South African Ministry of Health, responding to the countrywide medicine shortages, adopted what is called non-negotiables for the public health sectors. The non-negotiables list is a list of items that are supposed to be available at all times for the continued provision of safe and quality health services. These items include medicine, cleaning materials, as well as equipment and laboratory services. The Minister called for provinces to do sufficient budgeting and ring-fence these funds with the intention to minimise the recurrence of non-availability of essential goods and services for basic service delivery (NDOH 2012a:1).

For quality and efficient medicine provision the South African Pharmacy Council advocates the availability of pharmacists and pharmacist's assistants to take charge of the provision of medicines in the hospitals, community health centres and primary health clinics in an environment compliant with good pharmacy practice (South African Pharmacy Council 2010:2). However, in practice there have been several challenges regarding availability of pharmacists and pharmacists' assistants in public health facilities with hospitals and community health centres not having permanent pharmacists. In primary health clinics nurses are in the main the only available personnel responsible for the provision-, ordering-, control of and enabling access to medicines (International Council of Nurses 2011:1).

This situation has the potential for the consistent non-replenishment of medicine stock as nurses' primary function is to render nursing care depending on other health workers and support services for on-site provision and medicine supply management. Therefore, it will

be important that a study on the provision of essential medicines be conducted and proposal for a standard framework be developed to improve the availability of medicines.

1.3 STATEMENT OF THE RESEARCH PROBLEM

South Africa does not have a framework approved for use in the country to guide and facilitate measurement and provisioning of essential medicines. Each province manage the medicine supply differently as evidenced by Free State and Western Cape operating as trading entities which handles medicine procurement and provisioning as a business transaction meaning that health facilities are only able to procure medicines if they have budget available without budget the medicine stock is withheld until budget availability proof is confirmed, resulting in avoidable medicine stock outs whereas the other seven provinces utilise an in house state warehouse approach which provide facilities with medicine as ordered based on needs submitted servicing either all the three levels of care whilst others only serve the district health services. Under the in-house warehouse approach medicine budget is shared amongst all cost centres where there is under expenditure experienced funds are rearranged to complement the over expenditure pressure. The risk occurs when the organisation is unable to pay the suppliers and stock is withheld by the suppliers resulting in the medicine stock outs.

The utilisation of the different frameworks and procedures has led in practice to delayed delivery of medicines to the facilities as the consignments are routed through the medical depots and sub depots before dispatch to the health facilities. The results manifest as the medicine stock out that is experienced in the various provinces. This negatively affects the cure and treatment of communicable and non-communicable diseases. South African health system continues to experience problems with insufficient medicine stock availability in eight of the nine provinces. No known formal study has yet been conducted nationally to establish the cause of the problem and propose a standard framework for better provisioning of essential medicines within the district health services.

With the above mentioned problem the following questions arise:

- Why is there a shortage of medicine in the various provinces?
- How can these shortages be eliminated?

1.4 AIM OF THE STUDY

Develop a standardised framework for provision of essential medicines for the district health services in South Africa.

1.4.1 Purpose of the study

The purpose of the study is to determine the various provinces approach to the provision of essential medicines in order to develop a standardised framework for the country district health services with a view to improve essential medicines availability.

1.4.2 Research objectives

- Explore and describe the different provinces approaches in the provision of essential medicines.
- Make recommendations on a corrective measure to be implemented in order to improve the availability of medicine in the various provinces.
- Identify best practices to be incorporated into the framework for the provision of essential medicines for the district health services.
- Formulate a framework for the provision of essential medicines for the district health services.

1.4.3 Research questions

- Has there been adequate provisioning of essential medicines within the district health services?
- How do provinces approach the provision of essential medicines for the district health services?
- How can the South African Department of Health ensure sufficient medicine provisioning across the nine provinces district health services?

1.5 SIGNIFICANCE OF THE STUDY

On average, WHO Member States spend about half of their total health expenditure on medical products and up to 90% of the population in developing countries purchase health commodities through out-of-pocket payment. Improving access to and regulation of these essential health commodities is a prerequisite for universal health coverage and to the achievement of international goals relating to the unfinished agendas for maternal and child health, communicable diseases targeted by the Millennium Development Goals, and equally crucial in the face of fast growing burdens of non-communicable diseases and a rapidly ageing world population (WHO 2014:2).

Medicines are the second highest cost driver after the cost of employees in terms of budget allocation and expenditure. There is also high wastage of medicines due to poor stock management and expiry in the health facilities which would encourage prioritisation of improvement strategies and introduction of better mechanisms to manage medicine supply (MSH 2012:1.3). Many reports have alluded to the ineffectiveness of medicine depots in ensuring that essential medicines reach the facilities in time and in the required quantities. Further the results of the National Core Standards assessment conducted in South Africa in the year 2011 reflected that all primary health clinics and community health centres were unable to meet the compliance requirements including the availability of essential medicines and supplies (Matsoso et al 2015:85). As such it has become imperative that attention be focused on key issues including that of provisioning of essential medicines

The study will therefore contribute towards design of the framework for the provision of medicines within the Republic of South Africa district health services with the intention of improving the overall availability of medicine in the various provinces.

1.6 DEFINITION OF KEY CONCEPTS

1.6.1 Medicine

The Medicines and Related Substances Act (Act 101 of 1965, as amended) defines medicine as “any substance used in diagnosis, treatment, mitigation, modification or prevention of disease” (South Africa 2002).

1.6.2 Essential medicines

Essential medicines are defined as those therapeutic substances used in the diagnosis, treatment, mitigation, and modification of the majority of the diseases affecting the population. These medicines are referred to as essential medicines (World Health Organization 2016).

1.6.3 Responsible pharmacist

SAPC defines responsible pharmacist as a natural person who is a pharmacist and who shall be responsible to the council for complying with all the provisions of this Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision; as a pharmacist registered with council as the pharmacist answerable for all matters relating to safekeeping, control and issue of medicines in a particular institution (SAPC 2010:201).

For the purpose of this study the Responsible Pharmacist will be defined as the person who is in charge of Pharmaceutical Services or medicine provision including Depot Managers as well as Pharmaceutical Services Managers.

1.6.4 District health services

In terms of the National Health Act 61 of 2003 a district is a demarcated area within a province which may further be divided into sub-districts. For the purpose of this study, district health services can be defined as the health services offered within a demarcated area ranging from primary health care services up to district hospital level (South Africa 2003).

1.6.5 Medical depot (medical warehouse)

Medicine and Related Substances Act 101 of 1965 defines the warehouse as the institution utilised for storage and distribution of medicines for wholesale purposes. For the purpose of this study Medical Depot will be defined as a provincial store of medicine

from which the institutions order medicine and other medical consumables (South Africa 2002).

1.7 THEORETICAL FOUNDATIONS FOR THE STUDY

1.7.1 Research paradigm

In Polit and Beck (2014:6), the research paradigm is defined as the world view or general perspective on the complexities of the real world. This worldview can be naturalistic paradigm which promotes the belief that the reality is not fixed but constructed by individuals within a particular context as such subjective in nature and knowledge maximised when the researcher and the participants are interacting closely in the quest of knowledge or positivist paradigm which promotes that there is single objective reality which can be studied independent of those being researched and researcher not able to influence the research findings.

For this study the paradigm chosen is the naturalistic paradigm as the focus is on the experiences of the service delivery managers responsible for day-to-day provisioning of essential medicines within different settings and experience in order to produce in depth data rich understanding towards the development of a framework.

1.7.2 Theoretical framework

Theory is explained as an integrated set of defined concepts and propositions that present a view of phenomenon. Theoretical framework is a logical structure of meaning that will guide the study and consist of an integrated set of defined concepts and propositions that present a view of the phenomenon and can be used to describe, explain the phenomenon under study (Grove, Burns & Gray 2013:41).

This study for the provision of medicines is guided by the Pharmaceutical Management Framework adopted by the World Health Organization as developed by the Management Sciences for Health. The Framework is composed of selection, procurement, distribution and use components supported by the legal framework and management support across the value chain (MSH 2012:2).

1.8 THE RESEARCH DESIGN AND METHOD

1.8.1 Research design

Research design involves a set of decisions regarding what topic is to be studied among what population with what research methods and purpose thereof (Barbie 2013:116). According to Grove et al (2013:43), the research design is the blue print for maximising control over factors that could interfere with the study intended outcomes.

The type of design directs the selection of the population, sampling process, methods of measurement as well as the plan for data collection and analysis. The research design enables the researcher to obtain research participants and collect information from them to reach conclusions about a research problem. This research will be conducted as a qualitative exploratory, descriptive study through experiences of the managers responsible for provision of medicine.

1.8.2 Qualitative research design

According to Streubert and Carpenter (2011:20), qualitative research design is the design based on a belief in multiple realities, commitment to identifying an approach to understanding that support the phenomenon under study as well as participant view point limiting the disruption of the natural environment under study acknowledging the researcher's participation in the research process and reporting the data in a literary style with the participants' commentaries.

The focus of qualitative studies is on the meaning that the participants attach to their social world. Marshall and Rossman (2011:2) also confirm that qualitative research is typically enacted in a naturalistic setting focusing on context, is emergent and evolving as well as fundamentally interpretative. Savin-Barden and Major (2013:66) confirmed that the qualitative research paradigm subscribes to the view that reality is subjective and constructed by individuals and groups as such regard knowledge as the meaning participants assign to their lives and create reality as a social construct through dialogue and negotiation.

According to Barbie (2013:90), the purpose of conducting qualitative research can be exploration, description and or explanation of a phenomenon. Qualitative research design is suitable for the study on the framework for provision of essential medicines as the research is intended to explore and describe in an uncontrolled setting the experiences of the pharmaceutical managers responsible for provision of medicines towards development of a standardised framework for provision of medicines in the district health services.

1.8.3 Research approach action research

This study was executed with the involvement of the participants in reviewing and improving their practice environment with an intention to promote new strategies to ensure consistent medicine availability in the health facilities. The study intention was to improve the practice as well as the quality of health care through development of a framework to ensure consistent provisioning of essential medicines. Action research is useful in circumstances where participatory, democratic processes are required to develop practical knowledge and promotion of flourishing of individuals and their community's. Action research is about working towards practical outcomes and creating new forms of understanding. The characteristics of action research are participation and collaboration, human flourishing, focuses on practical issues, and reflexive in nature with intent for action leading to change (Taylor & Francis 2013:154).

Action research is reported to be problem focused, context specific, future oriented educative, deals with individual as members of the social groups involving a change intervention aimed at improvement and involvement recognising those involved as participants in the change process (Koshy, Koshy & Waterman 2011:29). Action research is not only concerned with doing things differently but also aspires to make judgement of the effectiveness of actions, existing and new (Townsend 2013:109). As such it was found to be suitable for studies focusing on development of framework for provisioning of essential medicines.

1.8.4 Study population

Barbie (2013:135) defines the study population as the aggregation of elements from which the sample is actually selected. Guest and Namey (2015:513) define the (study)

target population as the set of elements to which the researcher desire to apply the findings of the study.

The population for this study were the responsible pharmacists including provincial pharmaceutical services managers and medical depot managers covering various provinces of the Republic of South Africa. The core function of the study population is the provision of essential medicines.

1.8.5 Sampling

Qualitative studies including action research participants should be obtained through purposive sampling with the intention to identify and select key informants who on account of their position or experience have more information than regular group members (Barbie 2013:128). The participants for this study were identified through purposive sampling to ensure that they would be able to provide a rich explanation and description of the content under study.

1.8.6 Sample

Qualitative researchers aim for information rich data sources for their studies and utilise various non probability sampling designs to identify participants as the interest is on participants who meet the study needs, knowledgeable, able to articulate and reflective on the phenomenon under study (Polit & Beck 2014:284).

According to Neuman (2011:268), purposive sampling is appropriate for selecting unique cases that are especially informative in order to gain deeper understanding of the phenomenon under study.

For this study South African National Department pharmaceutical services, provincial pharmaceutical and medical depot managers were purposively selected as they have the knowledge and experience in the provision of medicines.

1.8.7 Data collection

Data collection is the process of gathering information relevant to the study using one of the following primary methods: participating in the setting, observing directly, interviewing in depth, and analysing documents (Marshall & Rossman 2011:137).

The data collection process in qualitative studies aim for rich, narrative accounts of the phenomenon under study. As such, the chosen collection method should capture the experiences and views of the participant in expressed words format (Streubert & Carpenter 2011:38). Conducting action research to understand and change the practice has an advantage that there is already data collected to be reviewed. Document analysis, observations, interviews, questionnaire completion, site visits and journal reviews are applicable as data collection tools (Townsend 2013:85). The view that data collection could be done in many forms, including interviews, observation, documents and audio-visual equipment for qualitative studies is supported by this author (Creswell 2013:177).

For this study data collection was executed through semi structured interview guide which was utilised to record field notes as well as participants biographical during interviews and site visits to the various provinces.

1.8.8 Data analysis

Qualitative data analysis is a search for general statements about the relationship and underlying themes in a study (Marshall & Rossman 2011:207). Data analysis in qualitative research consists of preparing and organising the data for analysis then reducing the data into themes through a process of coding and condensing the codes, and finally representing the data in figures, tables or discussion (Creswell 2013:180). Data analysis for qualitative studies progresses through classification of ideas, themes, topics, activities, and types of people as well as other categories relevant to the study (Schensul & Le Compte 2013:98). The goal of data analysis is to illuminate the experiences of those who have lived them by sharing the richness of lived experiences and cultures (Streubert & Carpenter 2011:47). Data analysis involves organising the data, preliminarily reading through of the database, coding and organising themes, representing the data in a meaningful format and forming of an interpretation thereof. These steps are

interconnected and form a spiral of activities all related to the analysis and representation of the data (Creswell 2013:179).

For this study data were analysed through reading and rereading the collected data to make sense of the data and classification of findings using themes categorisation in relation to the components of the pharmaceutical management framework towards production of the district health services framework for provision of essential medicines.

1.9 SCOPE OF THE STUDY

The study focus was on the provision of the essential medicines for the first level of care which is district health services utilising the framework for pharmaceutical services components of selection, procurement, storage, distribution and use taking into account the legislation and management support elements.

1.10 STRUCTURE OF THE THESIS

The thesis is comprised of seven chapters constituted as following:

Chapter 1: Orientation of the study

The chapter above presented an overview of the research study including the background, research problem, research process as well as the thesis structure.

Chapter 2: Theoretical framework

The chapter provide an overview and discussion of the pharmaceutical management theoretical framework as developed by management science for health for the provision of essential medicines that guided the study.

Chapter 3: Literature review

The chapter will present detailed literature review from an international, African and South African context on approaches and experiences with regard to provision of essential medicines.

Chapter 4: Research design

This chapter will provide an outline of the research design and the methodology followed in the research execution.

Chapter 5: Data analysis, presentation of research findings and discussion of action areas

The research finding based on the site visits conducted as well as practices observed in the provision of essential medicines will be presented utilising the theme approach taking into account the pharmaceutical management framework. Further in this chapter the action areas and interventions based on the research findings will be discussed.

Chapter 6: Presentation of the proposed framework for provision of essential medicines in the district health services

The proposed framework for the provision of essential medicines within the district health services will be presented in this chapter.

Chapter 7: Conclusion and recommendation for further studies

The conclusion and recommendations for further studies will be presented in this chapter.

1.11 CONCLUSION

The chapter gave an overview and orientation to the study in relation to the research problem of the provision of essential medicines, theoretical framework and the research design as well as methodology followed in undertaking the research project. In the next chapter the literature review content is presented and explained further.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Pharmaceutical purchases (medicines) are the key cost driver for the health care system, being second only to the compensation of employees in terms of the health budget high expenditure items (MSH 2012:18.3). It is undisputed fact that medicines are essential for the treatment of diseases and illnesses despite this fact, according to World Health Organization estimation, 1.7 billion people nearly one third of the world population have inadequate or no access to essential medicines. It is therefore; essential that the ability of pharmaceuticals to save lives, reduce suffering and improve health is ensured through strategies and processes at promotion of the likelihood that medicines are of good quality, safe, available, affordable and properly used all the time (WHO 2011a:4).

As part of efforts to improve access to medicines, provision of medicines is included in the Sustainable Development Goals under SDG 3: Ensure healthy lives and promote well-being for all at all ages specifically as *target 3.11: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all* (United Nations 2016:1). Access has been defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk of the population. The vision of the WHO Essential Medicines and Health Products Department (EMP) is closely aligned with SDG 3 by striving for a world where every child, man and woman can afford and has access to the quality medicines and health products they need to lead a healthy and productive life (WHO2014.1).

2.2 PROBLEM OF ACCESS AND PROVISION OF MEDICINES

Expenditures on medicines can represent up to 66 percent of total health spending in developing countries and could be a major cause of household impoverishment as up to 90 percent of such expenditures are out-of-pocket expenses. Today, over one-third of the world's population and over one-half of the poorest in Asia and Africa still lack access to essential drugs. According to the WHO, such access should cover the therapeutic, physical and financial aspects i.e. cover priority health problems, are available within easy physical reach and are affordable to all. For the poor in developing countries, availability and affordability of essential medicines are both key problems. Some fear that with the introduction of strong product patents for medicines through the world-wide uniform standards of the World Trade Organization, the Trade and Related Intellectual Property Rights Agreement, prices of essential drugs would be even higher and therefore, even less affordable for the poor. This is because such patents give their owner the right to exclude all others from unauthorised making, using, selling or distributing the product thus giving a 'legal monopoly' right. Further access to medicines will continue to be poor even in the absence of patents due to lack of adequate purchasing power and necessary infrastructure (WHO 2014:2).

The implications were reported to be serious for HIV/AIDS in developing countries where the access to life saving treatment is limited by cost due to patents and prices. An estimated 95 percent of those suffering from this disease live in developing countries where the disease is showing no signs of abatement. With over half of such persons belonging to the most productive age of below 25 years, this disease is causing serious social and economic consequences (WHO 2011a:4).

The fact that medicines are expensive requires that processes used to procure and distribute medicines are effective and efficient to maximise the benefits and use of medicines however; most health system strengthening interventions have ignored interconnections between systems components. In particular complex relationships between medicines and health financing, human resources, health information and service delivery are not given sufficient consideration.

As a consequence, populations access to medicines (ATM) is addressed mainly through fragmented often vertical approaches usually focusing on supply and unrelated to the

wider issue of access to health services and interventions (Bigdeli, Jacobs, Tomson, Laing, Ghaffar, Dujardin & Van Damme 2012:692). The results have been that medicines are often not available when needed. Studies carried out in Brazil have shown that on average 40 percent of the medicines prescribed in public primary health care were not available when needed (Bertoldi, Helfer, Camargo, Tavares & Kanavos 2012:2). As a result, when the medicines are not available and accessible the control and treatment of diseases is negatively affected resulting in the premature deaths and morbidity of the citizens.

MSF (2013:13) reported that lack of access to medicines has complex underlying factors ranging from health programme implementation to medicine supply system challenges. A study conducted on Pharmaceutical Management of Tuberculosis in seven of the nine provinces in the Republic of South Africa (RSA) found that the provision of essential medicines including Anti-Retroviral and Tuberculosis medication was not optimal at less than 95 percent in five of the provinces, namely the Free State, Eastern Cape, Gauteng, Limpopo, and Mpumalanga. The factors contributing to poor provisioning of medicines were especially in clinic settings poor stock control and management in nurse-led primary health clinics and a lack of pharmacist's assistants to take charge of drug supply management. Further a lack of electronic stock management systems also played a role as manual stock cards were found not to be updated at most facilities (Pure Health Consulting 2012:97).

In the Republic of South Africa only two of the nine provinces namely Western Cape and North West had adequate provision of above 95 percent availability for essential medicines. The factors that contributed to this included electronic stock management, maintenance of the 3 month buffer stock, close monitoring and weekly reporting on stock availability, active contract management and interaction with the suppliers over quantification, shortages and forecasting of needs, involvement of all role-players in medicine stock management including finance, programme managers and pharmacists as well as adjustment of issuing quantities during limited stock period to ensure that all patients receive medication whilst waiting for the replenishment stock (Pure Health Consulting 2012:129).

The available literature demonstrate that there have been several challenges regarding medicine supply in RSA, with various provinces reporting medicine stock outs to the extent that the inability to provide the required quantity and quality of medicines was identified as a key challenge facing the South African Government.

Although there have been some successes over the past three years, and the South African government has undertaken several initiatives to improve the supply chain for medicines, stock outs at primary healthcare facilities remain an undeniable threat to the health of the people of South Africa. Those most vulnerable to the effects of stock outs are usually poor and rural communities who depend on public facilities for health services. When these remote facilities experience stock outs, the impact goes beyond health: Patients often make repeated, costly trips to health facilities to keep up their prescriptions. Pharmacists and nurses spend more time rationing drugs instead of caring for ill patients. Babies are not vaccinated at times (Stock Out 2016:6).

This was confirmed by the Civic organisation report that revealed that medicine stock out is a national crisis affecting all the nine provinces in particular for the HIV and TB medicines, with rural provinces being the worst affected at 54 percent stock out rate and also suffering major stock out for the vaccines at 35 percent in November 2013 (MSF 2013:7-12). Further evidence from South Africa suggest deficiencies with the supply of medicines within the state sector as evidenced by medicines intended for use in state only facilities being found in the private sector. Such theft of pharmaceuticals in SA has been acknowledged by the government (Patel, Norris, Gauld & Rades 2008:547-549).

Internationally medicine provisioning problems have been reported in some states of Brazil including challenges in medicines distribution, where supply of public sector facilities is often problematic as evidenced by inadequate quantities, problems with frequency and time of distribution, and inefficient stock control among others. Further the lack of standard operational procedures for medicine stock management, no access restrictions to non-authorised personnel, lack of training to those working in the medicine store rooms and lack of technical criteria to select the medicines to be available to the population were reported (Bertoldi et al 2012:2). The study recommended that in order to control the problem of access to essential medicines decision makers need to realise that many factors play a role including patent protection, poor living conditions, lack of medical

facilities, proper infrastructure, malnutrition and lack of means for distribution and administration of medicines.

In the light of the prevalent shortage of medicines it is therefore; necessary that new approaches and models should be explored to ensure that medicines are accessible and affordable to the citizens of the country. Even in the RSA there are indications that medicine provisioning is not optimum in the district health services in particular at community health centres and primary health clinics. However; the District hospitals were found to have satisfactory medicine availability. The following factors affected negatively the availability of medicines: poor medicine stock management, late deliveries from the Medical Depot, poor communication amongst the role players, lack of electronic ordering systems, duplication of patients, medicine theft, transport and departmental red tape (Zuma 2013:91).

2.3 INTERNATIONAL WORLD HEALTH ORGANIZATION CONTEXT ON PROVISION OF ESSENTIAL MEDICINES

WHO has since 1978 Declaration of Alma Ata established a department of Essential Medicines which is responsible for monitoring member countries initiatives towards universal access and availability of medicines. The 2011 WHO Essential Medicine Availability report which is based on the standard methodology and focuses on essential medicines used in the majority of the member countries indicates that medicine availability across the WHO regions was reported at an average of 60 percent. In the Eastern Mediterranean region medicine availability scored 32 percent, with 58 percent in the European region. In the African and South Asian regions the average availability was less than 60 percent (WHO 2011a:4).

A study conducted in 36 countries reports that in the public sector the provision and availability of 15 generic medicines was found to be low, ranging from 9,7 percent in Yemen to 79,2 percent in Mongolia. The regional availability ranged from 29, 4 percent in Africa and 54, 4 percent in America. In the private sector the availability of generic medicine was lower, ranging from 50, 1 percent in the Western Pacific to 75,1 percent in South East Asia. The lowest availability of medication was recorded in Chad to be at 14,8 percent, Kuwait 36,3 percent, Philippines 33,6 percent and China ranging from 34,6 percent to 38,3 percent.

The mean availability of medicines was found to be generally lower in the public sector than in the private sector. The factors contributing to low availability of medicines in the public sector in particular relate to key processes required for effective provision of medicines including inadequate funding, lack of incentives to maintain stocks, inability to forecast accurately, inefficient distribution systems or leakage of medicine for private use. In the private sector the factors influencing medicine provisioning and access were mainly the price. However, the private sector demonstrated a high availability of generic medicines, such as recorded in Syria at 97, 5 percent and in Chennai, India, of 91, 8 percent. Factors contributing to improved access included setting of limits by the state on the price mark-up and elimination of taxes on medicinal products (Cameroon, Roubos, Ewen, Mantel-Teeuwisse, Leufkens & Laing 2011:416).

The United Nation reported that while the availability of generic essential medicines is limited especially in the public sector the situation with regard to medicine for treating chronic conditions is particularly worse. This is very disturbing given the fact that chronic diseases are the cause of no less than 40 percent of all deaths in low income countries. Moreover, only 27 percent of respondents from poor households in low-income countries who needed treatment for a chronic condition reported having received the treatment (UN 2011:52).

Gray and Manasse (2012:158) in recent commentary in a Belgian pharmacy journal claims that the problem is global – "from Afghanistan to Zimbabwe" – listing 21 countries affected by a variety of medicine supply problems. A shortage of the injectable antibiotic Streptomycin was reported in 15 countries in 2010, with 11 more countries predicting their stocks would run out before they could be replenished. This report states that there was a wide range of causes for medicine supply shortages (provisioning) some of which could be dealt with by government agencies. These shortages occur against a clear understanding that medicines are a critical commodity for maintaining the health status of citizens across the world. It should be free at a point of service for poor communities and accessible to all countries at affordable prices. Further, according to Mercurio (2007:23), the availability of medicine is also affected by inflated medicine prices due to tariffs levied by the production countries on medicine leaving their shores. In the Democratic Republic of Congo, the tax levied on medicine is 30 percent. Other countries including India, Sierra Leone, Nigeria and Bolivia also impose tariffs on the importation of pharmaceuticals, namely 55 percent, 40 percent, 34 percent and 32 percent respectively.

The charging of additional sales tax in countries including South Africa (14 percent), Argentina (21 percent), Bangladesh (15 percent), The Dominican Republic (28 percent), Greece (15 percent) and Turkey (18 percent) is another factor affecting medicine availability and access to medicine by individual patients. Due to poor medicine provisioning systems in the public health sector patients from lower income countries, including South Africa, are forced to buy medicine privately, where original brands are sold costing the public a possible four times the price of the generic medicines (WHO 2011b:7).

The non-availability of medicines in public health facilities and high cost of original brands result in patients from poor lower income countries being exposed to the risk of defaulting treatment and disease complications, which contributes to reduced life expectancy as well as premature mortality and morbidity. WHO further report that lack of access to medicines is not the only a problem. Less than one third of the oral contraceptives used globally are of the assured quality required in industrialised countries. In one Asian country, more than half of the ingredient combinations for malaria are fake. Moreover, even when medicines are available and of assured quality, they are not always used appropriately. In many countries up to half of all prescriptions are unnecessary or incorrect, and half of all patients do not take their medicines as prescribed (WHO 2010:1). The WHO made the following recommendations to facilitate lifesaving medicine's availability and access: improve financing and distribution efficiency, promote the use of generic products and control supply chain costs by limiting the mark-ups and remove duties and taxes on medicine. It is believed that improvement in the availability of medicine through these measures will contribute towards improving health outcomes including reduction of infant mortality, improving maternal health and combating HIV and AIDS, tuberculosis and malaria (WHO 2011a:2). The WHO further proposes a review of policies towards improving the availability of medicines, including the components of medicine selection, procurement, distribution, and financing. Financing models include promotion of the provision of free essential medicines and also the introduction of the insurance system, like medical aid and subsidies for different categories of the population (WHO 2011b:13).

2.4 WHO REGIONAL CONTEXT FOR PROVISION OF THE ESSENTIAL MEDICINES

WHO has divided the countries into five regions namely Africa, European, South East Asia, America, Eastern Mediterranean, Western Pacific (WHO 2015). In developing countries, pharmaceutical expenditures and drug procurements account for 20–50 percent of public health budgets.

Making essential medicines available for everyone at affordable prices is a key condition for improving national health indicators. Inadequate provision of medicine and medical supplies has a direct bearing on the performance of the health system. Corruption in procurement/distribution of pharmaceutical and medical supplies reduces access to essential medicines, particularly for the most vulnerable groups. WHO estimates indicate that approximately 2 billion people lack regular access to medicines and that improving access to medicines could potentially save the lives of 10 million people every year (WHO 2014:14).

2.5 WORLD REGIONS MEDICINE PROVISIONING CONTEXT

2.5.1 Essential medicines provision in the American region

2.5.1.1 *Brazil*

This country has population of at least 200 million as per 2013 census with a high risk of non-communicable diseases (WHO 2015). The studies carried out in Brazil have shown that on average 40 percent of the medicines prescribed in public primary health care were not available when needed. In this country medicine access relates both to affordability and availability (available stock of essential medicines in pharmacies). Availability particularly in the public sector remained an issue of considerable concern in Brazil, recent research found that for 71 percent of medicines the availability of generics was below 10 percent. International evidence, using data from 36 low and middle-income countries, showed that in the public sector, availability ranged from 29 to 54 percent and prices for private patients were 9 to 25 times higher than international reference prices for generics and 20 times higher for originator products.

In the public sector, a series of different procurement models is used by governments from developing countries to purchase medicines and other health products. An increasing number of countries have opted to decentralise the procurement process as an effort to answer to local needs. The decentralised purchase involves different levels of responsibility in the procurement process at the federal, state and city levels (Bertoldi et al 2012:2).

2.5.1.2 *United States of America*

This country has a population of 320 million also having a high prevalence of the non-communicable diseases including hypertension and cancer (WHO 2015). USA is regarded as a developed country, however does also experience poor provisioning and non-availability of medicine. Gray and Manasse (2012:158) reported that shortages of essential medicines, amongst them generic injectable chemotherapy agents are an increasing cause for concern in the country. The problem is said to be far greater, affecting other classes of medicines including injectable anaesthetic agents, nutrition and electrolyte products, enzyme replacement products and radio pharmaceuticals. Further Erin Fox, manager of the drug information centre at the University of Utah, states that the reported drug shortages are at its highest in a decade in the United States of America. The service is said to have recorded 211 new drug shortages, up from 70 shortages in 2006 and 166 in 2008. These shortages have an impact on patient safety and care standards with more than 1000 near misses and adverse patient outcomes reported (Larkin 2011:28).

The lack of some of the most basic medications has caused physicians to advise their patients to seek the medicines they need from locations outside the United States of America. Manufacturing quality problems have been implicated as one of the contributing factors in shortages of medicines produced by a limited number of suppliers, such as the influenza vaccine. Overall 43 percent of 127 shortages investigated by the United States Food and Drug Administration were attributed to manufacturing quality problems (Nash 2012:12).

The other factors contributing to the poor provision of medicines in the United States of America include medicine manufacturers depending on a small number of facilities for medicine production, Changes in procurement practices are also another factor (such as

insistence on the WHO prequalification status or registration with a stringent regulatory authority) which may invalidate a previous supplier as in the case of Streptomycin (Gray & Manasse 2012:158).

2.5.1.3 Mexico

A country with the population of 122 million whose leading cause of death is diabetic mellitus (WHO 2015). According to Wirtz, Russo and Escoban (2009:30) in Mexico, like many other developing countries access to and availability of medicines has been hampered by various factors including stock outs in the public health sector (especially for the uninsured population) as well as the out of pocket expenditure on medicines and the fragmentation of the Mexican health system. Access to and availability of medicine was further limited by the fact that at least 42 percent of the health services users had to pay for their prescribed medicines. Thus if the patient could not pay he will not obtain the required medicine. Over the years' population access does not seem to have improved significantly as the patients who had to buy medicines in private pharmacies increased from 42 percent in 2000 to 47 percent in 2006.

2.5.2 Eastern Mediterranean region medicines provisioning context

2.5.2.1 Sudan

According to the WHO data, the country has 38 million citizens and spend at least 6,8 percent of the budget on health. The availability of essential medicines in this country is relatively higher with medical stores and private pharmacies reporting the average availability at 100 percent, and 82 percent in public facilities (WHO 2015).

The high availability is enhanced by the existence of a central medicines store which is a governmental corporation responsible for ensuring that quality medicines are available at affordable prices through, amongst other strategies, the creation of dedicated funding for medicine, and the implementation of good procurement, storage, transportation and distribution practices. Parts of this country reporting lower medicine availability listed contributing factors as being the absence of drug (medicine) inventory cards, poor financial support for transportation and distribution from the central medicine store to the pharmacies (Elamin, Ibrahim & Yousif 2010:36).

2.5.3 Western Pacific region

2.5.3.1 China

China has at least 1,3 billion population with an average health expenditure of 5,6 percent with drug expenditures comprising up to 40 percent of total health expenditures ranking amongst the highest proportions in the world, however, the country experienced challenges with essential medicines provisioning.

Yang, Dib, Zhu, Gang and Zhang (2010:224) reported that the availability of low price generic medicine in the Hubei province was found to be 38, 9 percent in the public sector and 44, 4 percent in the private sector. Further, a field survey conducted in Shandong and Gansu provinces in 2007 revealed that the median availability of surveyed medicines in hospital pharmacies ranged from 19 to 69 percent. Moreover, the Chinese people have suffered from inaccessible and unaffordable health services for decades. By the end of 2012, there were still eighty thousand five hundred and twelve people, comprising approximately 6 percent of the population, who lacked access to health services (Li, Li, Zhu Fu, Xu, Wei & Chu 2015:345).

Another survey conducted in 2006 in Shanghai, China, revealed that the overall availability of medicine was poor in both the public and private sectors. Generic medicine was more readily available in the public sector than the private sector. The average availability in the public sector was 13, 3 percent for the innovator (non-generic expensive) brand and 33,3 percent for the lower priced generics respectively, whilst in private pharmacies the average availability for innovator brands was 10 percent and 15 percent for lower priced generics. The factors reported to contribute mainly to the poor provisioning include prescribers' preference of branded drugs rather than generic medicines in the public sector as evidenced by doctors not prescribing medicines on the essential lists resulting in essential medicines not being ordered for utilisation in public health facilities (Lu 2006:35).

In 2009 the government of China invested in large-scale health care reform to achieve universal health care coverage. One of the major reform components focuses on improving access to essential medicines to reduce high out-of-pocket medicines

spending. The reform policies were comprehensive, and included systematic selection of essential medicines to improve availability, centralised procurement and tendering at provincial levels, pricing policies, provision of essential medicines at cost in primary level facilities, and stronger quality and safety standards. While challenges remain, China's system sets an example of a comprehensive approach that other countries could emulate in reforming their health care systems and achieving universal coverage (Barber, Huang, Santoso, Laing, Paris & Wu 2013:1).

2.5.3.2 *Pakistan*

With a population of 182 million and health expenditure of 2,8 percent of the country's gross domestic product (WHO 2015). The country is affected in the provision of essential medicines by the lack of standard procurement systems and effective use and maintenance of health technologies for the primary health care network posing serious limitations to the delivery of quality care to an extent that the insufficient availability of medicines has detrimentally affected the use of public health services where a very limited proportion of public sector facilities had an uninterrupted flow of essential medicines.

According to the study conducted in 2010, there was insufficient availability of medicines which affected the use of public health facilities as there were few health facilities that had uninterrupted essential medicine supply. The author proposed that to enhance access to life-saving primary health care services, essential medicines should be procured in sufficient quantities along with improved efforts to reduce stock outs caused by improper procurement and transport, storage and management deficiencies (Sabih, Bile, Buehler, Hafeez, Nishtar & Siddiqi 2010:142).

Poor availability and erratic supply of medicines in the Pakistan government sector are rooted in several factors such as inadequate management to address the local needs, poor distribution at the level of local health facilities, corruption at the level of distributors and suppliers and inefficiencies in the supply and distribution chain and insufficient availability of medicines in appropriate dosage forms for children as found in other studies (Shafiq, Shaik & Kumar 2011:136).

2.5.3.3 *Philippines*

With a population of 98 million and health expenditure of 4,4 percent of the GDP (WHO 2015). In this country a 2009 study conducted using WHO methodology indicated that availability of essential medicines in the public health facilities was 53,3 percent. In the private sector it was at 100 percent, and in central district warehouses supplying the public sector it was 33,3 percent. The stock out duration for the public facilities was an average of 24, 9 days and 43, 8 days in the central districts warehouses respectively. The factors contributing to the insufficient provisioning were poor provisioning systems including non-centralisation of procurement from the district warehouses, as facilities could still bypass the warehouses to obtain medicines elsewhere, as well as high medicine prices in the country (Batangan & Juban 2009:34).

2.5.3.4 *Malaysia*

This country has at least 29 million populations and spends 4 percent of the GDP on health (WHO 2015). According to Babar, Ibrahim, Sing and Bukhari (2005:17), in the Malaysian public sector only 25 percent of the generic medicines were available in the 20 facilities surveyed. The factors contributing to the poor provisioning and low availability were under-regulation of medicine prices, uncapped mark-ups by health practitioners and poor monitoring for the provision and procurement of medicines on the National Essential Drug List. The pharmacist's role in ensuring the availability of medicine was also limited as medicine was freely available in private doctors' consulting rooms. However, stricter measures were imposed on medicine control and issuing by pharmacists. The country also did not have a national medicine pricing policy. The recommendations included that government should control mark-ups on generic brands and ensure that medicines on the National Essential Drug List are available in the public sector.

In summary within this region, the factors contributing to poor provisioning and low availability of essential medicines were:

- Poor quality of medicine in circulation as the strength of medicine available differed from the recommended strength in the WHO survey manual.
- Lack of supply from the manufacturers due to low government prices.
- Irrational use of medicine due to financial incentives.

- That profit driven prescribing physicians were prescribing more expensive medicines.
- The hospital centred issuing of medicine which led to low medicine availability in private pharmacies as patients were encouraged to obtain medication in hospital rather than in private pharmacies.
- That the policy on global budget control on pharmaceutical expenditure limited the procurement of innovator non-generic medicines.

2.5.4 Essential medicine provision context in the South East Asia

2.5.4.1 *Nepal*

Nepal is a low-income country in South Asia located between China and India. It has a population of 28.1 million of whom 44.2 percent are living below the poverty line as determined by the Multidimensional Poverty Index. A review of the free essential health care services programme reported that both the type and quantities of free essential medicines were insufficient for PHC facilities and district hospitals, expired medicines were present in health facilities and human resources were inadequate. Thus, there is a need to improve logistics, human resource capabilities and coverage of the essential medicines programme so as to improve access to and quality use of medicines to achieve the goals of the free essential health care services programme (Bhuvan, Haydon & Norris 2015:2).

2.5.4.2 *India*

A country with 1,252 billion populations spending at least 4 percent of their GDP on health (WHO 2015) has also experienced challenges with medicine supply and provisioning. Kotwani, Ewen, Dey, Lyer, Lakshmi, Patel, Raman, Singhai, Thawani, Tripathi and Laing (2007:645-654) in a study conducted in six sites in India, found that the average availability of core medicines in accordance with WHO methodology was low ranging between 30 percent in Chennai ,10 percent in Haryana, and 12,5 percent in Karnataka. The factors contributing the low availability and poor provisioning included poor consideration and disregard of the state essential medicine list in the prescription patterns by the clinicians, limited finances for medicine, inefficient distribution systems and

utilisation of different essential medicine lists by pharmacies leading non-availability of medicines prescribed by specialists.

It is recommended the following strategies to improve medicine provisioning and availability:

- That the country should legalise implementation of one country essential medicine lists to reduce the number of available medicine in the country.
- That the usage of generic medicines rather than the non-generic brands should be promoted.
- That pharmacists should be empowered to issue generic brand equivalents.
- The introduction of national regulation of medicinal prices.

2.5.4.3 *Summary of common factors affecting medicine provision and availability in the South East Asia*

The common factors identified were lack of national medicine policies, inadequate medicine distribution services, pricing, tax levies, use of expensive non-generic brands, unsubsidised medicine in state facilities resulting in out of pocket expenses, poor quality of medicines not compliant with WHO standards, and irrational prescribing by health professionals.

2.6 AFRICAN COUNTRIES' MEDICINE PROVISIONING CONTEXT

Over the years the African region has also experienced an alarming lack of essential medicines in the public sector, driving patients to pay higher prices in the private sector or stay without medicine to manage their ailments and diseases. In an attempt to turn around the situation, the African Region of WHO hosted a consultative workshop to explore ways to improve access to and availability of medicine. During this workshop the major contributing factor to medicine shortages was identified as African countries having weak or no mechanisms for essential medicine availability monitoring and evaluation (WHO AFRICA 2006:38). Reasons for persistently low access to medicines include inadequate financing, regulatory problems, lengthy procurement processes, lack of incentives for maintaining sufficient stock levels, poor logistics management (e.g., forecasting, distribution, information technology (IT) systems); corruption and lack of

qualified health workers to manage the medicines supply chain (Lubinga, Larsen-Cooper, Crawford, Matemba, Stergachis & Babigumira 2014:2).

The paragraphs below reflect on the medicine provisioning in the African Region:

2.6.1 Ethiopia

The country is amongst the poorest countries with 91 million population and spending only 3,8 percent of the budget on health (WHO 2015). In a study conducted by Daniel, Tegegnenwork, Demissie and Reithinger (2011:61) provision of continuous access to essential medicines, laboratory services and medical supplies was regarded as fundamental in addressing the health needs of the population. However, in 10 out of 48 (21 percent) of the facilities that were surveyed no malaria, tuberculosis or HIV medicines were available. The shortage of human resources and weak supply chain processes were reported as the main factors contributing to the shortage and poor provision of medicines in this country.

2.6.2 Malawi

Malawi has 16 million population spending 8, 3 percent of their Gross Domestic Product on health (WHO 2015). Lufesi, Andrew and Aursnes (2007:7) found that medicine necessary for treating pneumonia, malaria and sexually transmitted infections were out of stock for a period of 42 to 240 days per year. The main factors reported for these shortages were poor deliveries from the Regional Medical Store, poor medicine stock management practices, delays in the ordering of medicine, as well as lack of training and supervision in the facilities and medical stores.

This country is also affected by the shortage of pharmacists and pharmacist assistants in the provision of the essential medicines as evidenced by the 2011 Malawi Health Sector Strategic Plan report stating that there were only five pharmacists in the country's public health system and only 24 percent of the established positions for pharmacy technicians were filled (Lubinga et al 2014:2).

2.6.3 Kenya

In this country with the population of 44 million spending at least 4, 5 percent of the budget on health services, the public sector drug supply system has been reformed through the establishment of the Kenya Medical Supplies Agency (KEMSA) which is a body corporate with the mandate of developing and operating a viable commercial service for the procurement and sale of medicines and medical supplies to the public health institutions. Medicine Procurement and distribution for the Ministry of Health (MOH) is done by MOH Procurement and Supply Division through KEMSA an external procurement agency which has a drug storage and distribution system with a central warehouse in Nairobi and a well-developed network of regional depots and district drug stores (WHO 2015). Further a 2008 study by Kangwana, Njogu, Wasunna, Kedinge, Memusi, Goodman, Zurovac and Snow (2009:737) investigated the provisioning and availability of malaria medication in government facilities. The study showed that 25, 6 percent of the surveyed facilities did not have any of the four treatment packs in stock. The factors contributing to this stock out were mainly procurement failures and delays due to a shift made away from direct procurement towards open tender processes. This shift was intended to achieve value for money and increase competition amongst potential suppliers. The open tender system implementation was further delayed by difficulty to obtain compliant tender bids from the bidders. The recommendation from the study was that procurement processes should be strengthened and impact: cost analyses conducted before deciding on international open tenders as the processes can be of extended duration leading to medicine stock outs.

The WHO survey recommended that Kenya develop and implement a medicines pricing policy to achieve a greater level of transparency, uniformity and predictability in the pricing of medicines including the consideration of reference pricing for medicines in the private sector, periodically monitor the prices of medicines, as well as aspects of access to monitor the effects of interventions, develop and implement pro-poor interventions aimed at increasing access to essential medicines and importantly enhance the efficiency of the public procurement agency and establish supportive linkages with the mission sector procurement system. Wangu and Osunga (2014:441) confirmed that inappropriate selection, poor distribution, poor funding and irrational medicine use were the leading factors in the poor availability and provision of medicines in Kenya.

2.6.4 Uganda

The country has 38 million people and has high poverty prevalence thus dependent on government for health care services (WHO 2015). In Uganda the majority of the medicines and equipment for government health units are obtained from National Medical Stores (NMS) and the medicine budgets have been decentralised, with guidelines to protect them at all service delivery levels. However, demand for essential medicines far exceeds supply. The survey conducted revealed that not all prescribed medicines were obtained due to various reasons including public health pharmacies not having stock (WHO AFRICA 2006).

A review of drug management and procurement practices conducted in the period 2006 to 2007 at the Kilembe Hospital in the Kasese District revealed that there were frequent medicine stock outs in the health units ranging between 24 and 94 days on average. In addition, large quantities of expired medicine were found in most district level facilities. The factors contributing to this situation where the irrational procurement and provision of medicines not based on needs and requisition, and poor quantification and donor driven supplies without proper coordination with the recipient department to determine actual need. These practices led to the non-availability of essential medicines required for the treatment of prevailing conditions in the country (Tumwine, Kutyabami, Odoi & Kalyango 2010:559).

2.6.5 Nigeria

This country with a population of 173 million (WHO 2015) also faces the challenge of poor provisioning, low- and non-availability of medicine as evidenced by the health centres and primary health care centres reporting stock out of essential medicines. The factors cited for these stock outs include inadequate budgetary allocations for medicines, poor stock control in supply chain processes, poor quality medicine not containing the minimum required ingredients for effectiveness, poor value for money, uncoordinated government action and local non-availability of quality essential medicines. The country has developed a Ten Remedies Plan to improve availability, including establishing a dedicated fund for primary health care, direct procurement of medicines, and utilisation of a drug supply management cycle in the medicine management processes (Oluabunwa 2010:12).

2.6.6 Zimbabwe

This country has a population of 14 million situated within the three regions with more than 63 districts which are mostly rural environment. In terms of the systems for provision of essential medicines; Zimbabwe has a Central Medical Store at National Level. There are six public warehouses in the secondary tier of the public sector distribution. The country has two regional warehouses which services the three provinces, two rural and one metropolitan province. The other warehouses are in each of the four rural provinces and get their supplies form the regional stores. Procurement is done centrally and commodities are delivered to the two regional stores where transfers are made to the respective branch stores. However; the percentage availability of key medicines at the Central Medical Store (CMS) was 38 percent (Zimbabwe 2011:24).

2.6.7 Summary of common factors affecting medicine provisioning in the African Region

The pharmaceutical sector data included in country reports indicated that African countries generally had limited pharmaceutical production capacity, most depended mainly on imports and a diverse distribution chain, with some types of unauthorised outlets suggesting the presence of an informal market (WHO 2010:8). Further the provision of medicines in developing countries was reported to be undermined by several factors including poor medicine supply and distribution systems (Dixit, Jayshree, Ubedulla, Manohar & Chandrasekhar 2011:599-600). The unregulated pricing of medicines, donor driven availability of medicines with poor coordination with the recipient department, poor warehousing (medical depot) practices, lack of skills in quantification and medicine supply management, and shortage of skilled human resources to manage medicine stock were confirmed to impact on the availability and provisioning of medicines.

The main barriers to access essential medicines in Sub Saharan Africa are summarised to be as follows:

- Inadequate national commitment to making healthcare a priority from the national to the local levels remains one of the greatest barriers to increasing access to existing medicines.

- Inadequate human resources for health, including pharmacists and pharmacy technicians, is a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world.
- The international community has not provided adequate finance nor consistently fulfilled its existing promises to developing countries.
- A persistent lack of coordination of international aid reduces access to medicines.
- The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement may block access to affordable new medicines and vaccines.
- The current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries (Thompson & Ogbe 2012:2).

2.7 THE REPUBLIC OF SOUTH AFRICA'S NATIONAL CONTEXT OF MEDICINE PROVISIONING

South Africa has procured medicines and other pharmaceutical supplies for the public sector through the tender system. The public health facilities were hit hard by the medicine shortages in over the 2013/2014 and 2014/2015 financial years. Reasons for the shortages included failure of provinces to pay suppliers, inability of suppliers to meet the tender demands, lack of expertise to monitor activities along supply chain (Stock Out 2016:13). The problem of medicine supply challenges has been in existence prior to the effect of South Africa's democratic government dispensation in 1994, medicine policies were also in line with the fragmented provision of the health services model. This resulted in differentiated access and varied availability of medicines due to lack of standardised essential medicine lists. In 1996 the National Drug Policy (NDP) was developed and approved by the new government in line with WHO standard requirements of member countries developing and implementing national medicine policies. The primary objective for the NDP was that of ensuring the availability of essential medicines (medication) to all South African citizens. The NDP is supported by Standard Treatment Guidelines and the Essential Medicine List for each level of care to realise the provision of affordable essential medicines (South Africa 1996:3). The government is expected to ensure availability of generic essential medicine through implementation of incentives that favour generic medicines and their production in the country (South Africa 1996:10).

The NDP emphasises that for the consistent availability of medicinal treatment, there should be effective management of medicine stock; adequate budget for medicine, effective stock control and monitoring as well as the availability of adequately trained health professionals capable of issuing medicine to the health services consumers (South Africa 1996:28). In South Africa the major platform through which citizens' access basic health services and medicines has been identified as primary health care centres which are located within the district health services. The provision of medicines in the primary health care context has been free for all citizens since 1994 in an attempt to promote healthy living and improve life expectancy of the population (South Africa 1996:1). Achieving these objectives requires a comprehensive strategy that not only includes improved supply and distribution, but also appropriate and extensive human resource development. The implementation of an Essential Drugs Programme (EDP) formed an integral part of this strategy, with continued rationalisation of the variety of medicines available in the public sector as a first priority (NDOH 2012a:15.).

In practice there has been limited work done to assess the impact of the National Drug Policy although the original policy document committed to conducting regular evaluations of the NDP, no official comprehensive review of the South African NDP and its impact has been conducted since its adoption in 1996. The limited scope surveys that were carried out in all the nine provinces and six metros of SA in 2003, with the aim of determining the impact of the NDP at PHC level demonstrated that the availability of medicines was found to be on average of 82 percent of a basket of key medicines.

However significant challenges were noted in terms of stock control (for instance 50 percent of stock records were inaccurate) and rational medicines use (in 7 percent of facilities, 50 percent or fewer patients knew how to take their medicines). A marked increase in the proportion of patients prescribed an antibiotic was noted increased from an average of 25 percent in the 1996 to 1998 baseline surveys to 47 percent in 2003 (Padarath & English 2013:178).

2.7.1 Graphic representation of the Republic of South African medicines supply chain or provisioning

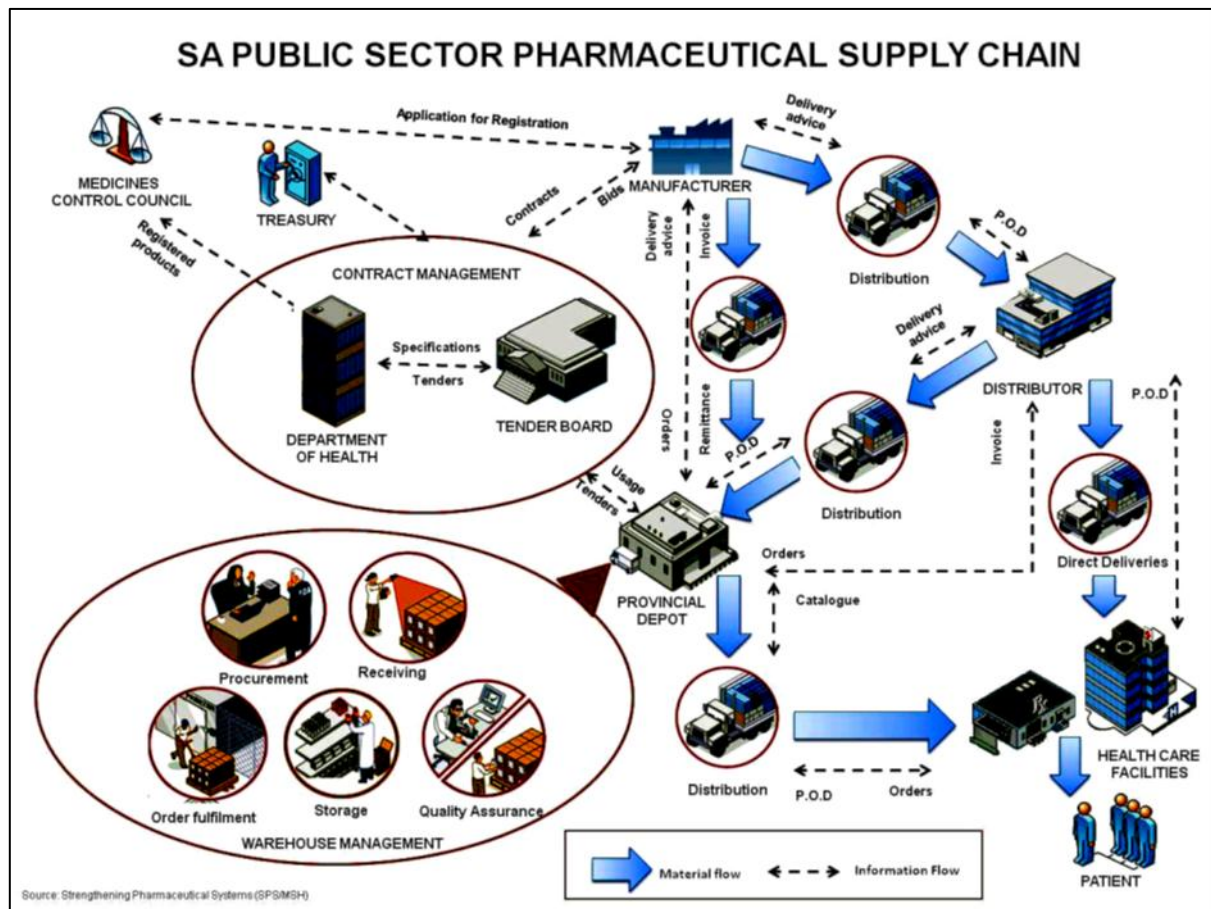


Figure 2.1 SA Public Sector Medicine Supply Chain
(SPS 2009)

In South Africa provision of medicines is governed by the Medicine and related Substance Act of 1965 as amended. The procurement of essential medicines for the public sector is done through the national tender system with provinces buying for the facilities falling within their areas of governance. The National Treasury has been responsible for awarding all contracts.

However, following reports of deterioration in medicines availability across the country, a Ministerial Task Team was established in 2009 to assess the state of medicines procurement in the public sector and make recommendations for procurement reforms (Padarath & English 2013:181)

The delivery of health care services in South Africa is a provincial government competence. This country has ten medical depots with Eastern Cape having two medical depots independently run by the nine provinces with an objective to ensure consistent supply of the essential medicines. These medical depots coordinate the procurement, distribution of the essential medicines including antiretroviral, tuberculosis, vaccines and chronic medicines and medical consumables namely gloves, syringes, injections and intravenous lines to the health facilities. There are different procedures and no standard model utilised in the procurement and distribution of medicines across the country. Provinces including Eastern Cape and Northern Cape procure for all the facilities within their provinces whereas Western Cape province procure primarily for the district health services as the larger hospitals are said to be well enabled to manage medicine and consumables supply utilising their own resources. It is likely that the imposition of any reform that includes central control of the pharmaceutical budget and of the medicines distribution chain is bound to be met with resistance (Padarath & English 2013:182). The government in 2009 realised the importance of medicine and medical supplies as an integral part of the provision of quality health care services to an extent that Medicine and medical consumables availability has been listed as one of the six priorities listed for the South African Department of Health (NDOH 2009a:1). This was done in order to improve the health profile of all South Africans.

Further improving medicine supply and management have been identified as key action point in the South African Health Programme of Action (NDOH 2009b:5). The Ten Point Plan of the National Department of Health further placed the emphasis on the review of drug policies which may lead to the improvement of medicine availability by means of improved procurement of medicines and the possible establishment of a state owned pharmaceutical industry (NDOH 2009b): Although the medicine policies are in place as reported by Padarath and English (2013:178) medicine availability has not been at an acceptable levels

During May 2010 South Africa experienced a shortage of over 80 medicines in the public health sector which included, amongst others, influenza vaccinations, medication for hypertension and tuberculosis. The severity of this shortage varied from province to province, as well as from hospital to hospital within the provinces, depending on the leadership abilities and skills levels of management (Health 24 2010).

The Public Service Commission results of the 2010 Citizen Survey also indicated that there were instances where citizens visited service delivery points and returned without receiving what they needed. Of the patient (10,5 percent) who participated in the survey were told to come the following day for their treatment, due to lack of sufficient stock of medicine or that it was time for staff to knock off for the day (Public Service Commission 2011:41). As the challenges with the health services provision, including medicine availability, continued to surface the need to strengthen District Health Services to become well-functioning was also identified as a core principle of primary health care re-engineering processes (Gray et al 2011:23). The re-engineering process, it is believed, will contribute towards the efficiency of district health services in the rendering of required essential services and will ensure that health programmes are available. This will include the provision of medicines, as well as treatment and care to the population in the areas where they live. The National Department of Health formally recognised that medicine availability is cardinal in the provision of quality health care services to the extent that medicine availability has been regarded as one of the six ministerial priorities required for compliance in all public health facilities (NDOH 2011a:16).

In further developments over the years the South African Government has also regarded Health as one of 12 key outcomes to be prioritised during the 2009-2014 government term of office towards ensuring a better life for all South Africans and the achievement of the Millennium Development Goals during the period 2010-2015 (GCIS 2010). In order to improve the health profile of all South Africans improved medicine supply and management have been identified as key factors in the South African Health Programme of Action. However, despite these developments; the negative media coverage on the non-availability and stock out of medicines gave the public health services a poor reputation as service users did not receive the expected medications as they visited health facilities (Thom & Langa 2010:7).

In 2011 the Ministry of Health commissioned a baseline audit for all public health facilities based on these standards. The purpose was to assess the current state of health services as well as the degree of compliance with standards. The results showed that the majority of health facilities did not comply with medicine availability standards due to stock out of essential medicines (Gray et al 2011:62).

Subsequent to the baseline audits in 2012, the Ministry of Health, responding to the countrywide medicine shortages, adopted what is called non-negotiables for the public health sectors. The non-negotiables list is a list of items that are supposed to be available at all times for the continued provision of safe and quality health services. These items include medicine, cleaning materials, as well as equipment and laboratory services. The Minister called for provinces to ensure sufficient budgeting and ring-fence these funds with the intention to minimise the recurrence of non-availability of essential goods and services for basic service delivery (NDOH 2012a:1).

For quality and efficient medicine provision the South African Pharmacy Council advocates the availability of pharmacists and pharmacist's assistants to take charge of the provision of medicines in the hospitals, community health centres and primary health clinics in an environment compliant with Good Pharmacy Practice (South African Pharmacy Council 2010:2). However, in practice there have been several challenges regarding availability of pharmacists and pharmacists' assistants in public health facilities with hospitals and Community Health Centres not having permanent pharmacists. In primary health clinics nurses are in the main the only available personnel responsible for the provision, ordering, control of and enabling access to medicines (International Council of Nurses 2011).

This situation has the potential for the consistent non-replenishment of medicine stock as nurses' primary function is to render nursing care depending on other health workers and support services for on-site provision and medicine supply management. Strengthening Pharmaceutical Services 2009:12) also reported that medicine stock outs were due partly to the little knowledge concerning management of medicines by the nurses who were responsible for the health centres including keeping of stock cards, ordering based on real consumption and also to the difficulties in procurement due to unavailability at the source and or lack of financial resources.

Matsoso et al (2015:198) advocate for a more effective role of the District Pharmacist as various studies suggest medicine stock outs at facility level. The authors believed district pharmacists could play a more influential role in medicine provisioning provided they are adequately resourced and recognised as key partners in district health services.

2.8 PROVINCES OF THE REPUBLIC OF SOUTH AFRICA'S SITUATION ON MEDICINE PROVISIONING

When assessing the number of provinces publishing availability details in their annual performance plans it becomes clear that not all nine provinces have readily available information on medicine shortages. Information regarding the medicine shortages usually emerges through the media when there are challenges with stock outs and as reaction to criticism by civil society lobby groups including Treatment Action Campaign and Section 27. The South African health system promotes the utilisation of the primary health care facilities as a first point of contact with the broader health system. However; numerous reports have highlighted the limited availability of essential medicines in particular at the primary health care settings which are located within district health services level across all the countries provinces. In the National Health Facilities Baseline Audit at least 86 percent of the health facilities were reported to be without the full package of the essential medicines including treatment for HIV and AIDS. Vaccines, Chronic Conditions and Tuberculosis (NDOH 2012a:57). The report published in December 2013 further highlighted the shortage of medicines across the country and cited the reasons as being lack of the uniform, standardised framework for the provision of medicines in South Africa especially for the district health services (SECTION 27 2012:14).

The Free State, Limpopo, Eastern Cape, Gauteng and Mpumalanga all experienced the medicine shortages during the 2013/2014 and 2014/15 calendar years (Stock Out 2016:8). A study conducted on Pharmaceutical Management of Tuberculosis in seven of our nine provinces found that provision of essential medicines was not optimal as the availability of ARV and TB medication was at less than 95 percent in five of the provinces, namely the Free State, Eastern Cape, Gauteng, Limpopo, and Mpumalanga.

The factors contributing to this low availability, especially in clinic settings, include poor stock control and management in nurse-led primary health clinics, and a lack of pharmacist's assistants to take charge of drug supply management. A lack of electronic stock management systems also plays a role as manual stock cards were found not to be updated at most facilities (Pure Health Consulting 2012:97).

Western Cape and North West were reported to have achieved above 95 percent availability. The factors that contributed to the better availability of essential medicines

include good systems for provision of medicines including electronic stock management, maintenance of the three month buffer stock, close monitoring and weekly reporting on stock availability, active contract management, and interaction with the suppliers over quantification, shortages and forecasting of needs, involvement of all role-players in medicine stock management including finance, programme managers and pharmacists and adjustment of issuing quantities during limited stock period to ensure that all patients receive medication whilst waiting for the replenishment stock (Pure Health Consulting 2012:129).

Between July 2012 and June 2013, the KwaZulu-Natal Provincial Pharmacy and Therapeutics Committee also faced a number of medicines shortages. The reasons for each shortage varied considerably, but each provides insight into the problem in a middle-income country with some local pharmaceutical manufacturing capacity (Gray 2014:209).

Further a study conducted in the Free State province demonstrated that there is inadequate availability of medicine in district health services due to various factors, including a shortage of pharmacists and pharmacists' assistants in the primary health setting, lack of delegation, red tape in the procurement of medicines, and lack of an electronic medicine procurement and monitoring system. Medicine Availability and provisioning thereof has been listed as a non-negotiable item and a priority for the South African Health sector requiring that consistent medicine availability is ensured at all times. It has been proposed that innovative plans and model should be developed to promote consistent medicine availability especially for the District Health System in which the majority of the citizens' access health services in a primary health clinic setting (Zuma 2013:99).

Further, Kheirandish, Rashidian, Kebriaeezade, Cheraghali and Soleymani (2015:119) submit that ensuring a reliable health care and supply systems for provision of medicines is critical and can be realised through "*Market monitoring enhancement*" which is implemented in different countries by various methods in order to identify more rapidly and accurately the market needs and medicine shortages in the country. The approaches include monthly collections of medicine consumption or distribution data, establishing an immediate warning system to detect the shortages, expanding the data collection network to all parts of the country, establishing an information centre for medicine shortages, developing working groups to review the country drug list appropriate to market needs,

increasing interactions with the pharmaceutical manufacturers and importers, for example via formal meetings and executing programs to receive customer complaints about medicine availability.

2.9 CONCLUSION

MSH (2012:8.5) suggests that at the district level the most relevant areas of strengthening within the pharmaceutical management cycle are distribution including storage and stock management as well as use. Matsoso et al (2015:198) reported that many reports have alluded to the ineffectiveness of medicine depots in ensuring that essential medicines reach the facilities in time and in the required quantities. As such it has become imperative that attention be focused on key issues including that of provisioning of essential medicines.

Therefore; it will be important that review of the systems for provision of essential medicines be conducted and proposal for a standard framework be developed to improve the availability of medicines especially in the district health services.

CHAPTER 3

THEORETICAL FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES

3.1 INTRODUCTION

Research studies have to be based on some form of a framework to guide the study. The framework is defined as an abstract, logical structure of meaning that guides the development of the study and enables the researcher to link the findings to the body of knowledge (Grove et al 2013:41). The framework can be conceptual or theoretical depending on the purpose and design followed. Conceptual Framework is defined as logical grouping of related concepts that is usually created to draw together several different aspects that are relevant to a complex situation whereas the theoretical framework is a knowledge form within the empirical form which is created to draw together several different aspects that are relevant to a complex situation (Chinn & Kramer 2011:246, 257). In this study the situation is the provision of essential medicines.

For this study a theoretical framework chosen was the Pharmaceutical Framework as developed and further refined by Management Science for Health in 2012 which comprise of the following aspects: Selection, Procurement, Distribution and Use of the provision of essential medicines guided by the legal framework.

3.2 THEORETICAL FRAMEWORK FOR DRUG (MEDICINE) SUPPLY MANAGEMENT

Management Science for Health in 2010 conducted extensive studies on medicine provision and availability across the world and after which the member states and regional consultations adopted a Medicine Supply Management Framework which is based on a four step framework which include activities for the selection, procurement, distribution and use as developed by the Management Sciences for Health.

At the centre of these processes are management systems, finance, human resources management, information management and policy governance functions (MSH 2012:1.8). This framework guides the provision of the medicines across the member countries in a holistic approach through clearly outlined processes for selection, procurement, storage, distribution and usage of medicine. When implemented properly the possibility of ensuring continuous access and provision of medicine is likely to be successful.

There has been further developments within medicine supply management sector towards refinement of the framework to guide medicine supply provisioning the development was facilitated by the MSH as the main organisation internationally lobbying for the medicine provisioning reforms and strongly advocating for the promotion of equitable access to quality medicine as both a key development challenge and an essential component of strengthening the health systems and primary health care reform in the world. The framework was finally adopted by World Health Organization in 2011. The purpose of the framework was to standardise processes within member countries for the medicine provisioning systems with an intention to ensure consistent medicine availability at all levels. WHO believed that to preserve lives it is a key principle that the provision and continuous availability of medicines be placed as an important priority that countries should design and implement the National Medicine Policies to guide selection, procurement, distribution and use of medicines. As a core component of the framework, the National Medicine Policy is regarded as an indication for political commitment and a guide for action that can demonstrate how the government will ensure that efficacious and safe medicine of good quality are affordable, accessible, available and rationally used (MSH 2012:1.9).

To this end the majority of WHO member countries including South Africa have approved national medicine policies.

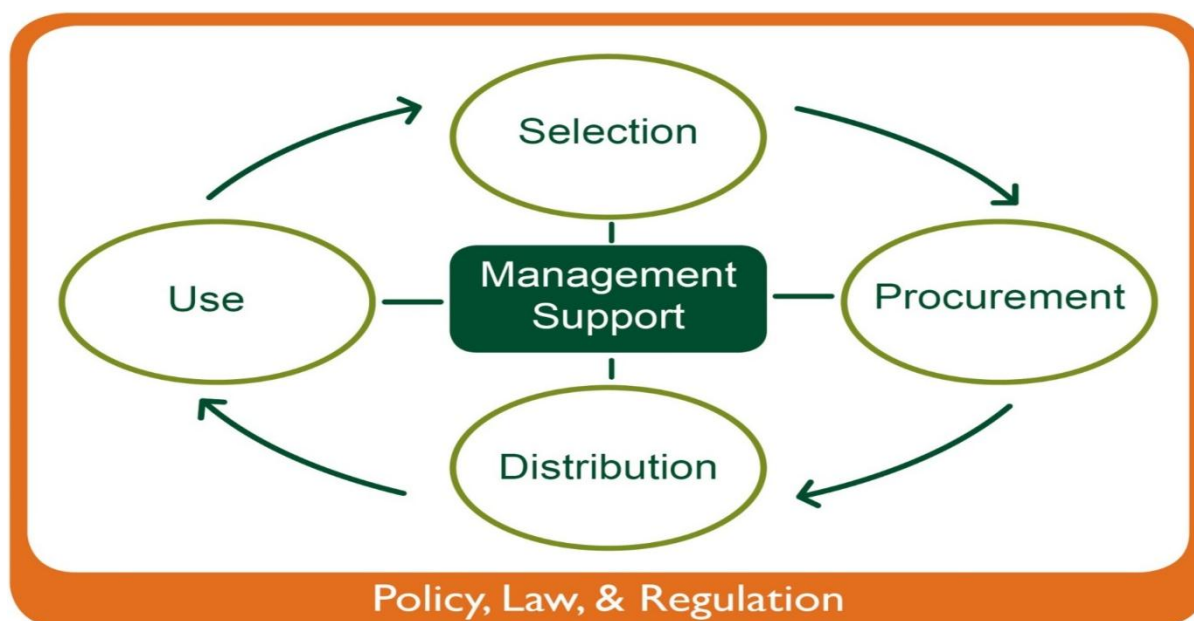


Figure 3.1 The pharmaceutical management framework
(Management Sciences for Health [MSH] 2012)

According to MSH (2012:1.10), pharmaceutical management framework comprises four basic functions: selection, procurement, distribution, and use. **Selection** involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual medicines and dosage forms and deciding which medicines will be available at each level of the health system. **Procurement** Includes quantifying medicine requirements, selecting procurement methods, managing tenders, establishing contract terms, and ensuring pharmaceutical quality adherence to contract terms. **Distribution** includes clearing customs, stock control, store management, and delivery to depots, pharmacies, and health facilities. **Use** includes diagnosing, prescribing, dispensing, and proper consumption by the patient. In the pharmaceutical management cycle, each major function builds on the previous function and leads logically to the next. Selection should be based on actual experience with health needs and medicine use; procurement requirements follow from selection decisions, and so forth.

At the centre of the pharmaceutical management cycle is the core of related management support systems, including the planning and organisation of services, financing and financial management, information management, and human resource management. These management support systems hold the pharmaceutical management framework together.

Although individual parts of the framework may function independently for a short time, the cycle as a whole will soon cease to operate and patient care will suffer without effective leadership, a functional organisational structure, adequate and sustainable financing, reliable management information, and motivated staff. The entire framework rests on a policy and legal components that establishes and supports the public commitment to essential medicine supply. The WHO member states subscribe to the above framework to manage provision of essential medicines. The paragraphs below will discuss each component and reflect key requirements for consistent provision of essential medicines.

3.2.1 Selection component

The framework for medicines has to provide for the selection process of essential medicines. Selection should be based on thorough discussions and acceptance by a multidisciplinary committee of experts who has the ability to interpret data and evaluate safety and efficacy of medicines within their area of expertise. The selection of the medicines depend on many factors including the prevalent diseases, treatment facilities, training and experience of the available personnel, financial resources, population genetic ,demographic and environmental factors. The outcome of selection component is the essential medicines lists (EMLs) which support the systematic delivery of medicines in the health-care system (MSH 2012:16.2).

The selection process of the WHO Model List of Essential Medicines has evolved since 1977 from expert evaluation to evidence-based selection that includes: systematic review of evidence of efficacy and safety; consideration of public health needs, availability and costs; and a transparent process. The Model List and its supporting documents serve as a valuable resource for advocacy, selection, purchasing and supply at the country level. In 2016, according to the World Health Organization report, all 194 countries had a national EML and the majority had been updated in the previous five years (WHO 2016:1). The model list has been expanded to include the WHO Model List of Essential Medicines List for Children (EMLc), to address the priority health-care needs of children (WHO 2016:1).

WHO member countries have developed what is referred to as **national lists of essential medicines**. The lists are commonly used in public sector procurement across all countries and in high-income countries for public insurance reimbursement. However, only a small fraction of countries use the EML for reimbursement for private insurance. All responding countries reported having a committee for the selection of medicines for the national EML. It is important that the EML is regularly updated to ensure that it is relevant to the health needs of the population, adapted to changes in therapeutic modalities, concordant with local treatment guidelines, and aligned with the logistics and budget of the health system.

The WHO survey showed that 69 percent of responding countries had updated their list within the previous five years. 81 percent of low-income countries had revised the EML within the past five years. The production of a national EML can help countries make the best use of limited resources to procure and make available the most appropriate treatments for the priority diseases and conditions. However, regular revision is essential to ensure that the selection remains current and credible (WHO 2011a:6). The concept of essential medicines provides the parameters as to which medicines should be included in the country list. These should be the medicines to treat the major diseases and conditions that affect the population and those that the health system can afford.

3.2.1.1 Benefits and impact of the coordinated selection of medicines

MSH (2012:16.4) highlights the benefits and advantages of limited selection of essential medicines can be categorised into the following categories supply, prescribing, organisational and patient use.

3.2.1.1.1 Supply

Easier procurement, storage and distribution, lower stock levels better quality assurance and easier dispensing.

3.2.1.1.2 Prescribing

Training of the prescribers will be more focused and simpler with the limited basket of medicines for use to an extent that professionals will gain more experience with fewer medicines. There will be non availability of irrational treatment alternatives, reduced anti

microbial resistance as well as focused medicine education and information and better identification of adverse medicine reaction.

3.2.1.1.3 Organisational benefits

The selection and specifying the type and number of pharmaceutical to be purchased will lead to an improved quantification process. There will be lower costs due to more competition to provide the limited medicine lists.

3.2.1.1.4 Patient use

The limited essential medicine selection and lists will promote medicine availability and reduction in the treatment confusion and further improve adherence to treatment as patients will have fewer medicines to comprehend as well as patient education will improve with focused education efforts and limited guidelines.

3.2.2 Procurement component

Effective procurement process is meant to ensure the availability of right medicine in the right quantities at reasonable prices and in compliance with the recognised quality standards. The procurement process is an integral part of the supply chain and pharmaceutical cycle. Good procurement is dependent on selection of the appropriate medicines. It is also important to ensure that the medicinal needs of the country are based on a strong quantification system.

A reliable supply chain system makes it possible to track the status of deliveries, stock, and consumption. It is important that the data from the users and adherence to standard treatment guidelines (STGs) is utilised as a measure of consumption data to be used for the next round of forecasting and selection (Van der Walt 2014:8).

The process of purchasing supplies utilises National, Multinational, private or public suppliers, global agencies depending on availability and costs. Purchasing through global agencies require that mechanisms are put in place to ensure that the quality assurance and control requirements are met to protect the service users and countries through

procurement planning, purchasing inventory control traffic, receiving, incoming inspection and salvage operations (MSH 2012:18.6).

3.2.2.1 Procurement cycle

The procurement cycle involve the following 10 steps:

1. Review medicine selections to determine quantities needed
2. Reconcile needs and funds
3. Choose procurement method
4. Locate and select suppliers
5. Specify procurement/contract terms
6. Monitor order status
7. Receive and check medicines
8. Make payment
9. Distribute medicines
10. Collect consumption information

Where the procurement cycle is followed the outcome is likely to be an effective procurement process for medicines which will ensures that:

- the right medicines in the right quantities are sourced
- the buyer-seller relationship are managed in a transparent and ethical manner
- the lowest practical purchase price are sourced
- all pharmaceuticals procured meet recognised standards of quality
- there are timely delivery to avoid shortages and stock-outs
- there is supplier reliability with respect to service and quality
- the purchasing schedule, formulas for order quantities of purchasing are set at each level of the system
- there is efficiency in the procurement processes

3.2.2.2 Medicine sourcing – procurement strategies

Sourcing of medicines could be done through open tender, restricted tender, competitive negotiation or direct procurement as explained below:

3.2.2.2.1 Open tender

A formal procedure by which quotes are invited from any supplier's representative on national or international, subject to the terms and conditions specified in the tender invitation.

3.2.2.2.2 Restricted tender

In a restricted tender, interested suppliers must be approved in advance, often through a formal prequalification process that considers adherence to good manufacturing practices, past supply performance, financial viability, and related factors.

3.2.2.2.3 Competitive negotiation

In competitive negotiation, the buyer approaches a limited number of selected suppliers (typically at least three) for price quotations. Buyers may also bargain with these suppliers to achieve specific price or service arrangements. For example, global organisations such as UNICEF, the Clinton Foundation, and supply chain management systems (SCMS) have successfully negotiated reduced prices of antiretroviral (ARV) medicines with manufacturers.

3.2.2.2.4 Direct procurement

Involve direct purchase from a single supplier, either at the quoted list price or at an agreed standard discount off the list price. For single-source medicines (generally those under patent with no licensing agreements that allow other firms to manufacture the medicine), the buyer basically has two choices namely direct procurement or selection of an alternative drug product (MSH 2012:18.6).

3.2.3 Distribution component

Distribution is meant to ensure a consistent of medicines and supplies to the facilities where they are needed whilst ensuring that resources are used in the most effective manner. Distribution system or framework has four elements which are system, information, storage and delivery elements (MSH 2012:22.2).

The decision of which distribution system will be utilised has to take into account the geographic coverage ,land type and distance, population coverage in terms of persons numbers as well as level of the health systems.

The distribution system has four major elements:

- **System type** which refer to a geographic and population coverage number of levels within the health system and situation analysis of whether processes are centralised or decentralised.
- **Information systems.** The information systems should be able to capture, generate data to demonstrate inventory or stock control to enable production of consumption reports and as far as possible have linkage between the warehouse systems and that of the health facilities.
- **Storage systems.** The environment under which the medicines are stored whilst awaiting distribution has to ensure that the medicines are protected from breakages,extreme heat or cold temperature and exposure to the external elements.The storage system should take into account selection of appropriate sites for storage, building design and layout for optimum temperature and movement of stock as well as the material handling systems for effective order picking and processing.
- **Delivery systems.** These should be developed taking into account the whether medicines will be collected by facilities or delivered by the warehouse utilising organisational resources or outsourced to the third party as well as the routes and scheduling of deliveries. The decision whether to utilise in house or third party should consider type of vehicle, mode of transport required whether road or air, need for vehicles procurement and maintanance which the health department may not necessarily have a skilled resource to manage.

3.2.3.1 Distribution system options

There are two options for distribution it can either be a push or pull systems (MSH 2012:22.9).

3.2.3.1.1 Push system

Push system is achieved by procuring and distributing standard pre-defined quantities of essential medicines for routine use .In the push system operational units are expected to supply certain stock and consumption information to the supply source so that issuing officers can plan allocations when supplying areas with limited access, limited management information system, and/or diversion and theft. Delivery plan is made at the beginning of a planning period (usually a year) and supplies are delivered according to the plan.

Conditions

- Staff members at the lower level of the distribution system are not (yet) competent in inventory control.
- Demand greatly exceeds supply, making rationing necessary.
- A limited number of products are being handled.
- Disaster or epidemic relief is needed, or the situation calls for short-term supply.

Transition from a push system to a pull system is recommended once management capacity and record-keeping improve.

3.2.3.1.2 Pull system

Pull system is a system through which facilities placed orders from a central warehouse based on the minimum and maximum ordering quantities at regular intervals.

Preconditions for success of the pull system

To be effective this system requires that field staff members are regularly supervised and performance monitored,good data should be available to decision makers,Staff members

at the lower level of the distribution system should be competent in quantifying and forecasting needs and managing inventory, sufficient supplies are available at supply sources to meet all programme needs and there must be capacity to handle large range of products.

3.2.4 Distribution cycle

According to MSH (2012:2.5), distribution cycle is a continuous process comprising of the following processes:

- Procurement of medicines and commodities to facilitate availability for delivery to the health facilities.
- Port clearing include identification of shipments as soon as they arrive in port ,processing of all importation documents, completing any customs requirements,storage of medicines properly until they leave the port, assessment of the shipment for losses or signs of damage and after clearance has been issued medicines can then be collected.
- Reception and Inspection the new shipment should be kept separate from other stock until inspection has been completed to check for damaged and missing items further the assessment for compliance with contract conditions regarding medicine type, quantity, presentation, packaging, labeling is also executed.
- Inventory control processes facilitate coordination of the flow of pharmaceuticals through the distribution system with key objectives of ensuring protection against theft and corruption and facilitate, requisitioning and issuing of medicines, financial accounting and preparing consumption and stock balance reports.
- Storage promotes proper location, construction, organisation, and maintenance of storage facilities in order to maintain medication quality, minimise theft and loss through damage and maintain regular supply to health facilities.
- Requisition utilise either a push or pull system through forms and procedures which are key components of the inventory control system and provide audit trail for tracing the flow of medicines.
- Delivery options can be warehouse staff or collected by health facility staff depending on the cost effective choice made by the entity.

- Dispensing the distribution process achieves its purpose when medicines reach hospital wards, outpatient clinics, health centers, or community health workers and are appropriately prescribed and dispensed to patients.
- Consumption reporting is a closing link in the distribution cycle enabling flow of information on consumption and stock balances back through the distribution system to the procurement office for use in quantifying procurement needs.

3.2.4.1 Good distribution practices

Engelbeen and Makhado (2014:20) recommend that In order to ensure that medicines reach the end users, the following needs to be implemented:

- Maintain a constant supply of medicines.
- Conserve medicine quality throughout the distribution process by ensuring that the cold chain is maintain and medicines are protected from the external elements and adverse weather conditions.
- Minimise loss of medicines through implementation of controls and tracking of the stock movements as well as prevention of theft in transit as well as in the facilities and warehouse and maintain accurate inventory records by full documentation at every stage and rationalise storage points for medicines.
- Provide information for forecasting medicine needs.
- Incorporate a quality assurance programme distribution costs are a significant component of the expense of running a public health supply system.
- Distribution costs below 5 percent of the medicines price are generally considered acceptable for essential medicines in public sector systems.

3.2.5 Rational medicine use component

According to WHO (2016:1), the rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

WHO (2016:1) further advocates for 12 key interventions to promote more rational use:

- Establishment of a multidisciplinary national body to coordinate policies on medicine use
- Use of clinical guidelines
- Development and use of national essential medicines list
- Establishment of drug and therapeutics committees in districts and hospitals
- Inclusion of problem-based pharmacotherapy training in undergraduate curricula
- Continuing in-service medical education as a licensure requirement
- Supervision, audit and feedback
- Use of independent information on medicines
- Public education about medicines
- Avoidance of perverse financial incentives
- Use of appropriate and enforced regulation
- Sufficient government expenditure to ensure availability of medicines and staff.

Further, according to Bradley and Mogano (2014:26), pharmaceutical management elements of rational medicine use include the following processes:

- A clinician making a diagnosis of a patient's sickness based on presenting complaints, history taken, physical examinations and other investigations conducted.
- Choosing appropriate medicine(s) for the diagnosed condition, and writing this as a prescription.
- A dispenser (pharmacist or nurse) interpreting the prescription, selecting the appropriate medicines and packing and labelling them, and counseling the patient on correct use.
- The patient taking the medicines as instructed.

Many factors influence rational use, and it is essential to formulate an overall policy for rational use of medicines and detailed procedures to address each of the component areas.

MSH (2012:27.2) identified the following criteria to be complied to promote rational medicine use:

- Prescription is based on sound medical considerations.
- Due consideration for safety, efficacy suitability for the patient and cost factors.
- The dosage, duration and the administration route should be appropriate for that particular medicine.
- Patients should be assessed for contra indications to avoid and minimise adverse drug reactions.
- There should be correct dispensing of medicines meaning treatment for the right patient for the right condition and appropriate information given to the patient with regard to the prescribed medicines.
- Patients should adhere to the prescribed treatment instructions.

3.2.5.1 *Proposed strategies to promote rational medicine use*

There are mechanisms and strategies to promote rational medicine use (MSH 2012:27.5) including the following:

- There must be a national multi-disciplinary structure to coordinate medicine use policies to serve as advisory structure as well as monitor the medicine use practices to promote rational medicine use.
- There must be standard treatment guidelines developed and implemented to ensure that the prescribers are guided to make sound and cost effective decision with regard to specific conditions.
- Clear mechanism for developing and revising essential medicine lists based on the treatment of choice.
- Establishment of Pharmaceutical and Therapeutic Committee in the districts and hospitals with clear responsibilities for promoting and monitoring rational use of medicines.
- Use problem based training in Pharmacotherapy based on national standard treatment guidelines starting with the undergraduate levels.
- Mandatory continuous professional development for all health professionals licensing requirements to include rational medicine use content.

- Develop mechanisms to regulate prescribing patterns in the private sector through regulation and collaboration with professional societies.
- Supportive rather than punitive supervision, monitoring and evaluation mechanisms including prescription audit and feedback, peer reviews and professional syndicate groups engaging in self-identification of medicine problems and solutions in a group should promote rational medicine use.

3.2.6 Legal framework component

To protect the public from harmful health practices government, need to approve comprehensive law and regulations and establish national regulatory authorities to ensure that the manufacturing, trade and use of medicines is regulated appropriately and that public has access to safe medicines and accurate medicine information. World Health Organization standards require that countries develop and implement national policies and standards for the provision of medicines in order to ensure safety of the population. All 194 member countries had medicine policies of varying quality (WHO 2016:1).

Makhado (2014:13) reported that the medicine policy has to consist of the following components:

- Legislation and regulations inclusive of country medicine control acts, establishment of statutory bodies, licensing procedures for medicines and practitioners, medicine quality control, quality assurance and trade regulations.
- Medicine selection for each level of care namely primary health care, district hospital services and tertiary hospital services.
- Pricing taking into account options of non-tax levies for medicines and use of generic versus brands utilisation.
- Human resource development in terms of categories of staff responsible for management and supply of medicines.
- Research incorporating medicine patent rights and production of new medicines.
- International cooperation guidelines with other countries in terms of trade and medicine movement between countries and levy tariffs.
- Rational medicine use, procurement, distribution.
- Monitoring and evaluation mechanism.

In the South African context there is Medicine and Related Substance Act of 1965 governing the manufacturing, licensing and sale of medicines in the country supported by various professional acts including Pharmacy, Nursing and other health related occupations. The National Drug Policy for South Africa was approved in 1996 to strengthen provision of medicines in the country and emphasised that the legal framework has to provide for establishment of the regulatory bodies with the functions of defining role of various parties, licensing, inspection and quality control, pharmaco vigilance monitoring and management of adverse medicine reactions, advertisement and promotions, sanctions (South Africa 1996:6-7).

3.2.7 Management support component

This component is concerned with management support systems including the planning and organisation of services, financing and financial management, information management, and human resource management. These management support systems hold the pharmaceutical management framework together (MSH 2012:38.2) further explained below.

3.2.7.1 Planning and organisation of pharmaceutical services

The management support component should address the planning, implementation and monitoring and evaluation elements to be effective. Planning is the process of analysing the current situation, assessing the needs, establishing the goals, setting the objectives and measurable targets, determining the strategies, responsibilities and resources needed to achieve the results in this study which is to ensure availability of medicines. Planning is addressed at three levels namely: strategic, programme and work levels looking at pharmaceutical supply systems assessment to understand the as is situation in order to identify strengths and weakness of the current medicine provisioning system, pharmaceutical management programmes, planning for pharmaceutical management, contracting pharmaceutical service providers, analysis and control of medicines expenditure, financial planning and management and infrastructure in terms of building storage facilities (MSH 2012:38.2).

3.2.7.1.1 Strategic planning

This component is concerned with the long-term future of the organisation and its overall effectiveness in the light of changing internal and external environments usually executed when current strategies are not working and possibly when there is a crisis in service delivery platform the outcome may be production of new policy.

3.2.7.1.2 Programme planning

Programme planning follows strategic planning focusing on medium term planning detailing expected outcomes, responsibilities, time frame, and budget.

3.2.7.1.3 Work planning

Work planning is a short-term looking and involves more the operational staff who is responsible for the programme or intervention implementation. The work plan has limited set of objectives with indicators for monitoring and measuring progress and results.

The planning process enables the organisation to ensure that the medicine supplies required are available, limit the crisis management and minimise the occurrence of medicine stock outs due to poor planning.

3.2.7.2 Contracting pharmaceutical service providers

Contracting should always be based on carefully prepared specifications and enforcement of contract terms to result in effective and efficient procurement. Further for day to day services the arranging contract especially for non-core services such as warehousing and transport functions.

The contracts for consideration is supply agency where all warehousing and transport functions are performed by private organisation on behalf of the company, direct delivery warehouse procures but goods are delivered directly to the hospital or district ,primary distribution is utilised when facilities order directly from the approved distributor paying the manufacturers and distributions fees directly without going via the warehouse and pharmaceutical benefit programme is the provision of prescribed services to designated

beneficiaries directly or by appointing agents utilising the mail or courier services (MSH 2012:39.2).

3.2.7.2.1 Contracting process

The process has four stages:

- Identification of service that could be provided by contract providers and undertaking a feasibility study for contracting out.
- Prepare clear tender specifications and contract terms.
- Shortlist suitable qualified suppliers, invite formal tenders and appoint service providers following due processes.
- Monitor the contracted provider and health system performance.

3.2.7.3 Organisation management

This component focuses on security, medical stores (warehouse), hospital pharmacy and broader health pharmaceutical management (MSH 2012:43).

3.2.7.4 Security management

This component is meant to prevent theft bribery and fraud and require that security assessment be conducted to identify sources of security breaches, decide on methods to improve security, analyse cost implications and potential savings and monitor the implementation of the chosen security measures.

3.2.7.5 Warehouse management

This component is meant to ensure that the flow and reliability of supplies from source to the end user is economical and consistent with minimal theft, compromised quality and wastage.

According to MSH (2012:44.2), good practices in warehouse management should include the following:

- There should be full management structure for management of the warehouse operations.
- The staff should be appropriately qualified, well skilled, exposed to continuous development, well disciplined and appropriately rewarded.
- There should be concise and well written standard operational procedures and guidelines.
- The work environment should be well structured to promote easy movement of stock whilst ensuring security.
- Warehouse demarcation to provide for environmental compliance and stock security.
- Stock should be kept in orderly traceable system compliant with First in First Out or First Expiry First Out.
- Periodic stock count.
- Housekeeping should be well maintained through regular cleaning, pest control, controlled disposal of damaged and expired stock, recording of stock movement and tight security measures.
- Stock should be kept in compliance with the manufacturer instructions including kept off the floor using pallets, pallet racks, shelves and cold chain maintained.

3.2.7.6 Hospital pharmaceutical management

The medicines in the hospital setting is managed through the Pharmaceutical and Therapeutic Committee whose responsibility is to develop policies and procedures for rationale medicine use which should be chaired by a senior clinician. The PTC should comprise of the multidisciplinary team members including pharmacist administrators, quality assurance coordinators and nursing and medical health professionals. The hospital pharmacy should be managed by a pharmacist who is responsible for procurement, storage and distribution of medicines within the hospital (MSH 2012:45.2).

3.2.7.7 General principles for managing pharmaceutical management in health facilities

At every health facility the following should be complied with:

- There should be proper security and storage of the medicines.
- Compliance with the environmental storage requirement.
- Accurate record keeping for stock movement.
- Proper systems for facilitating reordering mechanisms.
- Systems for effective stock rotation and expiry monitoring.
- Mechanisms for prevention of theft and fire hazards (MSH 2012:46.2).

3.2.8 Information management

Medicine provision should be based on consumption information to promote proper procurement and consistent medicine availability. The strategies used for information management include monitoring and evaluations, use of pharmaceutical management information systems and computer technology (MSH 2012:48).

3.2.8.1 *Monitoring and evaluation*

This activity is a continuous process utilising the following approaches:

- Supervisory visits for monitoring of progress in the implementation of medicine supply work plans.
- Routine reporting on key data through the pharmaceutical information systems.
- Sentinel sites for more detailed reporting on new initiatives for.
- Conduct special studies when indicated by variance availability of medicines or eruption of problems.

3.2.8.2 *Pharmaceutical management information system*

Pharmaceutical management information system is an organised system for collecting processing, reporting and using information for decision making (MSH 2012:49.2).

The system should comply with the following processes:

- The record keeping documents should be a combination of registers, ledgers and filing systems.

- Information reporting forms including periodic status reporting used for transmission of data to relevant departments for management decision making.
- Feedback mechanisms to the information generating units.
- The system should be able to integrate with other systems to ensure efficiency and facilitate data utilisations.

3.2.8.2.1 Computers in pharmaceutical management

Personal computers can be used in all aspect of pharmaceutical cycle When used effectively computers save money, promote efficiency and improve the quality of service however if poorly planned or implemented the results are wastage of resources, decreased efficiencies and limited improvements in management processes

3.2.8.2.2 Guidelines towards successful computerisation

MSH (2012:50.4) advises that the following should be considered and undertaken to ensure successful computerisation:

- An assessment should be conducted to determine required software before purchasing hardware to ensure suitability and prevent wastage due to incompatibility.
- There should be locally available support for both hardware and software in order to reduce downtime due to system failures.
- Back up manual system should be available to enable uninterrupted service delivery in case of unforeseen downtimes.
- Capacitate staff through training on the computer system and involve the team in the development and migration of the computer systems Implement in phases to allow for staff adjustment in the computerisation process.
- Mechanisms should be put in place to ensure back up of files, data, equipment as wells as virus protection.
- There should be funding available for supplies replenishment, system hardware, and software upgrades and staff development on latest technologies.

3.2.9 Human resource management and capacity development

3.2.9.1 *Human resource management*

Human resources play a critical role in medicine provisioning across the whole chain from manufacturing to the utilisation. In the pharmaceutical sector the goal of human resources management is to develop and sustain adequate supply of skilled and motivated employees to provide quality service (MSH 2012:51.2).

The strategies used for effective HRM include:

- Empowered supervisors able to manage day-to-day operations and develop staff to better efficiency levels.
- Standard operation procedures for performance management and career progression leading to job satisfaction
- Standard job descriptions and post requirements per level of care
- Clear labour relations management procedures to manage discipline, dealing with grievances and handle conflicts.
- Standing engagement meeting and communication procedures.

3.2.9.2 *Designing and implementing training programme*

Training programmes are essential component of human resource management as change in procedure occur consistently owing to technology and new treatment innovations.

The need for training could be indicated due to need for continuous professional development to maintain professional registration and changing circumstances or protocols. Training programme design should be preceded by needs assessment taking into account the following three steps:

First step: observation of staff in action, seeking the staff and service users or clients' opinion on the work processes allowing submission of innovation proposals for consideration, identifying work performance problems and analysis of job descriptions and performance reviews reports.

Second step: Training learning objectives need to be designed stating clearly what skills should the participants demonstrates on training programme completion.

Third and final step result in the training programme design completion and implementation to improve performance (MSH 2012:52.2).

3.3 CONCLUSION

The theoretical framework for provision of pharmaceutical services as developed by management sciences for health will be used in presenting the research findings as well as basis for developing the framework for the provision of medicines within the district health services.

CHAPTER 4

RESEARCH METHODOLOGY

4.1 INTRODUCTION

The previous chapters one to three provided the orientation of the study, literature review as well as the theoretical framework of the study. This chapter will present the methodology utilised in the conduct of the study including research design, population, sampling as well as the data collection, analysis strategies and ethical considerations.

4.2 RESEARCH DESIGN

Research design involve a set of decisions regarding what topic is to be studied, among what population, which research methods will be utilised in the execution of the study and purpose thereof (Barbie 2013:116). The research design is the overall plan according to which researchers obtain answers to the research questions and handling challenges that can undermine the study evidence. The research design is the architectural backbone of the study indicating aspects of the study including data collection and the setting for the study (Polit & Beck 2014:51). The research design, according to Grove et al (2013:43), is a blue print for conducting a study that maximise control over factors that could interfere with the validity of the findings. This study project was conducted as a qualitative exploratory, descriptive study through experiences of the managers responsible for provision of essential medicine across eight of the nine provinces of South Africa in an attempt to obtain data rich explanations and details of approaches used in order to develop a framework for the developing countries.

4.2.1 Philosophical assumptions

Grove et al (2013:10) define philosophy as means that provide a broad, global explanation of the world and believes that meaning is produced by perceptually putting the pieces together to make the whole and confirmed that because perception varies with individuals, many meanings are possible. Philosophical assumptions refer to the view of reality and knowledge that in turn inform researcher perspectives, approaches and methods as well clarify the reason the researcher choose a particular research design

(Savin-Barden & Major 2013:54). The researcher believe in that the experience of the frontline practitioners should develop the practice further as such an approach as defined by Streubert and Carpenter (2011:20) that promote multiple realities, accepting that the researcher is part of the discovery process , valuing the subjective views of participants , with special interest in the description and data rich narratives as well as the various context under which the research phenomenon is experienced was preferred for the study.

The researcher intended to reflect on the practice of provision of essential medicines within the district health services utilising the experiences of the managers on the coal face in order to develop new knowledge with regard to the phenomenon under study as such a research paradigm promoting interpretive insights and thick description as well as reflective practice and interaction between theory and practice towards transforming practice was favoured for this study. The research paradigm identified was qualitative research. The researcher in the conduct of the study was an active participant engaging with the participants in unpacking and creating the social reality. The researcher believed that the knowledge developed through mutual engagement of interdependent individuals interested in improving practice would have bigger impact on the service delivery platform.

4.2.2 Qualitative research design

According to Streubert and Carpenter (2011:20), qualitative research design is the design based on a belief in multiple realities, commitment to identifying an approach to understanding that support the phenomenon under study as well as participant view point limiting the disruption of the natural environment under study acknowledging the researcher's participation in the research process and reporting the data in a literary style with the participants' commentaries. The focus of qualitative studies is on the meaning that the participants attach to their social world. Marshall and Rossman (2011:2) also confirmed that qualitative research is typically enacted in a naturalistic setting focusing on context, is emergent and evolving as well as fundamentally interpretative. According to Barbie (2013:90), the purpose of conducting social (qualitative) research can be exploration, description and or explanation of a phenomenon.

Qualitative research designs have the ability to generate richly nuanced, personal or public level data through selection of knowledgeable informants, open ended questioning about their attitudes and experiences and inductive probing of their experiences (Guest & Namey 2015:444). Qualitative research design is a naturalistic enquiry which is usually less obstructive than quantitative investigations and does not manipulate the research setting.

4.2.3 Qualitative exploratory, descriptive and design

Qualitative research designs in health enable the exploration of health and illness as they are perceived and experienced by the people themselves. Qualitative research is used to expose emotions, perspectives, beliefs and values as well as action and behaviours to understand the participant's response and meaning to the phenomenon under study (Morse 2012:21). Descriptive research studies involve identifying and understanding the nature of phenomenon as well as relationships in a narrative style (Grove et al 2013:12).

As this research was conducted through experiences of the managers responsible for provision of medicines. The design used should provide for in depth narrative and content rich data. Qualitative research design was found suitable for the study on the framework for provision of essential medicines as the research was intended to explore and describe in an uncontrolled setting the experiences of the managers responsible for provision of medicines towards development of a standardised framework for provision of medicines in the district health services. Further the qualitative research design was utilised as it allowed for the respondents to share first-hand experiences of the subject under investigation to produce narrative rich data.

4.3 RESEARCH APPROACH ACTION RESEARCH

The study intended to improve the practice as well as the quality of health care through development of a framework to ensure consistent provisioning of essential medicines. Action research was found useful in circumstances where participatory, democratic processes are required to develop practical knowledge and promotion of flourishing of individuals and their communities with an intention for action that lead to change (Taylor & Francis 2013:154). In its pure definition action research can be explained as a qualitative research method whose purpose is to engage in a problem solving through a

cyclical process of thinking, acting, data gathering and reflection requiring participants to be empowered and emphasis is on leading a social change (Savin-Baden & Major 2013:255). McNiff and Whitehead (2009:11) define action research as a systematic enquiry undertaken to improve a social situation utilising processes of improvements and making claims that something has improved and then made public. Action research is characterised by the intention to produce change in practice with the involvement of the stakeholders within a specific context working together towards practical outcomes and creating new forms of understanding.

The characteristics of action research are participation and democracy, human flourishing, focus on practical issues, knowledge in action and emergent development form (Reason & Bradbury 2011:2). Action research is reported to be problem focused, context specific, future oriented, educative and deals with individual as members of the social groups involving a change intervention aimed at improvement and involvement recognising those involved as participants in the change process (Koshy et al 2011:29). The principle of collaboration feature prominently in the conduct of action research in that those who have a stake in the problem under study must actively participate in developing action plan to improve the practice (Herr & Anderson 2015:4). Action Research is suitable as an approach employed by practitioners for improving practice as part of the process for change enabling the researcher to learn and share newly generated knowledge with those who may benefit from this knowledge (Koshy et al 2011:9).

This study was conducted with the involvement of the participants in reviewing and improving their practice environment with an intention to promote new strategies to ensure consistent medicine availability in the health facilities. Action research is not only concerned with doing things differently but also aspire to make judgement of the effectiveness of actions, existing and new (Townsend 2013:109). Further action research can be useful in developing innovation, improving health care, developing and understanding in practitioners as well as involving of users and staff (Reason & Bradbury 2011:390). As such it would be applicable in studies focusing on development of framework for provisioning of essential medicines.

For this research the best results were obtained through action research in order to promote active involvement of the informants in the process of the development of the

model for provision of essential medicines so that the improvement in the practice environment can be sustained and implemented by the end users.

4.3.1 Action research sub-types

Action research can be categorised to the following:

Insider action research is the kind of action research conducted by a member of that community with the participants from within. Usually prompted by the frustration or contradiction within the workplace which the practitioners have been thinking about for some time (Herr & Anderson 2015:92).

Outsider action research is executed by an external person from a particular community together with those community members in order to generate knowledge and make contribution to the community or setting under study (Herr & Anderson 2015:95).

4.3.2 Action research stages or cycles

Action research has six stages not necessarily progressing in a linear approach including refining a focus, conducting reconnaissance (a stage during which the researcher attempt to understand the issue of interest in more depth to be able to develop comprehensive plans for the project execution), reflecting on progress, planning for action, implementing and observing action, reflecting and evaluating change (Townsend 2013:19). The cycle for action research include Identification of the issue of concern, reflection, planning for the action reflect, decide on the action, implement the action, discuss the action with those involved, reflect and evaluate the impact of change, interpret processes involved in the whole cycle and plan next action (Savin-Baden & Major 2013:252).

According to Francis and Taylor (2013:154), the following observable actions should be experienced. During planning a plan is developed that will inform action to improve current practice; this plan should be flexible and be adaptable to unforeseen effects or constrains. The action resulting from the research should be deliberate and controlled promoting future development. The researcher is expected to observe the effects and constraints of the action. There should also be reflection on the processes, decisions and outcomes

achieved as well as the problems encountered and implications thereof for future practices.

Koshy et al (2011:79) has condensed the stages of action research into four phases namely Identification of an issue and setting up a project, reflection, planning stage and evaluation stage as explained below:

4.3.2.1 Identification and setting up a project

Herr and Anderson (2015:86) identify the following activities to be executed in a pilot study format testing of the research question, methodologies conduct initial data gathering and analysis the content of this face can form part of the final research report and enables the researcher to establish relationships with the participants for the study. During this stage the problem is identified for possible change implementation, introductory literature review and reflection is carried out. In this phase the researcher will conduct literature review, obtain ethical and research site approvals as well as prepare for the entry and rapport development to the research site. Baseline data collection, analysis and site visits will also be done during this period. As an outcome of the identification phase for this study a research proposal was developed, finalised and submitted for approval based on the literature review. Ethical clearance was granted by the university and the research sites which were followed by a pilot study and mini research conducted to further refine the research questions and tools to be used for data gathering.

4.3.2.2 Reflection stage

Reflection is a continuous process of identifying the problem aspects of practice, review the practice and find constructive ways to deal with the practice problem identified. Action researchers are judged on whether they reflected on what was researched, testing own judgement against the critical feedback of others thus enabling self-learning from the participants (McNiff & Whitehead 2009:14). For this study the researcher and the participants worked together to identify practice challenges through joint discussion and review of the collected data obtained through the interview and site visits towards developing new ways of providing essential medicines for the district health services. The reflection process was undertaken continuously during the research project lifespan.

4.3.2.3 Planning and implementation stage

This stage involves drawing up a conceptual map of the action research. A research proposal is usually developed during this stage. Further entry will be negotiated with the settings in which the research would be conducted to ensure that the problem under study is essential to the community as well as to establish collaborations for the improvement of practice (Herr & Anderson 2015:4). For the purpose of this study the researcher conducted in depth interviews and site visits with the provincial depot responsible pharmacists/managers and heads of pharmaceutical services (HOPS) in the health services setting focusing on the provision of medicines across the eight provinces in the Republic of South Africa with an intention to identify best practices to be incorporated into the framework. As reflected in the phases of action research, interviewing, reflection and focus group discussions are key methods for data collection suitable for this study.

Marshall and Rossman (2011:93) state that although interviewing is often supplemented with other data collection methods, the primary objective is to capture the deep meaning of experience in the participant's own words. Herr and Anderson (2015:5) submit that action research take the form of an intervention process utilising a spiral of action cycle involving development of an action plan to improve practice, implement the action plan, observe the effects of the action in the context in which the action occur and continuous reflection on the effects as a basis for further planning, subsequent action through a succession of cycles.

4.3.2.4 Evaluation stage

During this stage the group evaluate the project in terms of the implementation of the activities that were planned. Townsend (2013:109) submitted that this stage contributes towards understanding what effect the particular practice or initiative has had. The participants were engaged at least twice during the research project lifespan to assess whether there have been developments on the practice improvement initiatives that were identified with the participants. This process enabled execution of member checking which is the practice of verifying the data collected with the participants of the study. Braun and Clarke (2013:284) submit that this process contribute to enhance the trustworthiness of the research process as well as data collection.

During the evaluation stage, the data obtained from the site visits and interviews across the provinces of the Republic of South Africa was analysed to identify common themes and best practices towards developing a framework for provision of essential medicines for district health services.

4.4 STUDY POPULATION AND SAMPLING

4.4.1 Study population

Barbie (2013:135) defines the study population as the aggregation of elements from which the sample is actually selected. Guest and Namey (2015:513) define the (study) target population as the set of elements to which the researcher desire to apply the findings of the study. The population for this study was the responsible pharmacists including the provincial pharmaceutical services managers and medical depot responsible pharmacists. The core function of the study population is management of the provision of essential medicines activities and operations.

4.4.2 Sampling framing

A sampling frame is a list of units composing a population from which a sample is selected (Barbie 2013:144). Guest and Namey (2015:513) also define the sampling frame as the listing of the entire target population.

The subjects in the qualitative research are called participants or informants for the purposes of the study. Qualitative studies including action research participants should be obtained through purposive sampling with the intention to identify and select key informants who on account of their position or experience have more information than regular group members (Barbie 2013:128). The participants for this study were identified through purposive sampling to ensure that they would be able to provide a rich explanation and description of the content under study.

4.4.3 Purposive sample selection

Purposive sampling is a non-probability sampling procedure in which elements are selected from the target population on the basis of their fit with a specific set of inclusion

or exclusion criteria (Guest & Namey 2015:522). Purposive sampling was used to identify and select the individuals that have more information than the regular group members. The selected subjects should present information rich cases from which the researcher can learn a lot about the central focus of the study. Barbie (2013:128) defines purposive sampling as the selection of the sample on the basis of knowledge of the population, its elements and the purpose of the study. According to Neuman (2011:268), purposive sampling is appropriate for selecting unique cases that are especially informative in order to gain deeper understanding of the phenomenon under study.

For this study, provincial pharmaceutical and medical depot managers were purposively selected as they have the knowledge and experience in the provision of essential medicines.

4.4.4 Research setting

The research was conducted in the eight of the nine provinces of the Republic of South Africa as sites responsible for provision of essential medicines. The depots and pharmaceutical services offices in these provinces were found suitable as they are the platform under which medicine provisioning is implemented as such provided the best sites, data and the practices to inform the development of the framework.

This setting provided a suitable environment for the conduct of the study and allowed for observation and an in-depth understanding of the problems faced by the participants regarding medicine provisioning.

4.5 DATA COLLECTION

Data collection is the process of gathering information relevant to the study using one of the following primary methods: participating in the setting, observing directly, interviewing in depth, and analysing documents (Marshall & Rossman 2011:137). The data collection process in qualitative studies aims for rich, narrative accounts of the phenomenon under study. As such, the chosen collection method should capture the experiences and views of the participant in expressed words format (Streubert & Carpenter 2011:38). Conducting action research to understand and change the practice has an advantage that there is already data collected to be reviewed. Document analysis, observations, interviews,

questionnaire completion, site visits and journal reviews are applicable as data collection tools (Townsend 2013:85).

For this study, data collection was executed through individual managers' interviews using an interview guide to collect the biographic data and responses to key discussion points as well as site visits to various provinces to review and observe the processes involved in the provision of essential medicine. The face to face interviews were chosen because of the possibility for full range of communication including response to non-verbal signs observed (Harding 2013:33). Creswell (2013:177) also support the view that data collection could be done in many forms, including interviews, observation, documents and audio-visual equipment for qualitative studies.

4.5.1 Site visits

The researcher submitted the request to all nine provincial pharmaceutical services and medical depots managers for participation and permission to conduct site visits to observe, analyse practices on essential medicine provisioning and also engage in discussion and interviews with the managers to explore and develop a framework for the district health services, however eight out nine provinces responded positively towards participation with one province non response despite numerous requests and follow ups.

4.5.2 Interview guide

Despite the flexibility that is a hall mark of qualitative data collection, there is still a need to prepare an interview guide to guide the interview which could be developed with full questions or reminder of topics to be discussed during the interviews (Harding 2013:36). The researcher usually has a list of topics or broad questions that must be covered in an interview as such the interview or topic guide is used to ensure that all question areas are addressed for semi structured interviews (Polit & Beck 2014:290).

For this study, the interview guide attached as Annexure D was developed based on the Pharmaceutical Framework components namely: selection, procurement, distribution, use, legal framework and management support covering the hospital, community health centres and primary health care clinics within the district health services context. The

questions and the data collection process as well as the site visits were based on these components.

4.5.3 Semi-structured interviews

Marshall and Rossman (2011:93) recommend that, in order to capture the individuals' lived experiences, an in depth interview should be used to capture the deep meaning of experience in the participant's own words indicate that qualitative research uses a flexible questioning approach. Although a basic set of questions is designed to start the project, the researcher can change questions or ask follow-up questions at any time as flexibility is the special strength of field research (Barbie 2013:347). The interviews were conducted using the semi structured interview approach in order to explore the experiences of the participants.

The process was expounded by providing the respondents with an interview guide to capture demographic details, as well as to record responses to certain predetermined questions. The interviews for this study were conducted in the environment in which the participants work utilising audio recording facilities.

There were various advantages to face to face in depth interviews namely that the researcher could view behaviour in a natural setting, excluding the artificiality that sometimes surround experimental research, and fostering of social support networks as the participants engage and reflect on the research topic under discussion (Marshall & Rossman 2011:150). Furthermore, this approach was believed to have potential to increase the depth of understanding that the researcher could gain from the experience.

4.6 DATA ANALYSIS

Qualitative data analysis is a search for general statements about the relationship and underlying themes in a study (Marshall & Rossman 2011:207). Data analysis in qualitative research consists of preparing and organising the data for analysis then reducing the data into themes through a process of coding and condensing the codes, and finally representing the data in figures, tables or discussion (Creswell 2013:180). Data analysis for qualitative studies progresses through classification of ideas, themes, topics, activities, and types of people as well as other categories relevant to the study (Schensul

& Le Compte 2013:98). The stages involved in qualitative data analysis are the following reading, rereading the data and comparing aspects to understand the content, taking into account the research aim and questions underline key segments and provide descriptive comments, matching the identified segments across the database, attach labels and identification of sub groups and finally assess the grouping against the current literature and theory towards presentation of the research findings (Grbich 2013:261).

The goal of data analysis is to illuminate the experiences of those who have lived them by sharing the richness of lived experiences and cultures (Streubert & Carpenter 2011:47). Data analysis involves organising the data, preliminarily reading through of the database, coding and organising themes, representing the data in a meaningful format and forming of an interpretation thereof. These steps are interconnected and form a spiral of activities all related to the analysis and representation of the data (Creswell 2013:179). The aim of data analysis is the discovery of patterns among the data including trends or changes over time or possible causal links amongst variables (Barbie 2013:411). These patterns would point the researcher to theoretical understanding of phenomenon under study.

4.6.1 Study data analysis processing

The process of data analysis in qualitative research moves from description to interpretation through some identified process (Grbich 2013:259). For this study the data analysis was executed through the review of data collected and reflection on the practices observed and recorded during the site visits and clustering in accordance with the components of the Pharmaceutical Management Cycle to identify common themes and best practices towards the development of the framework for the provision of essential medicines for the district health services. The data collected were then transcribed from the transcripts made of digital recordings and notes that were collected. The data were then organised and analysed by means of an inductive model in order to ensure that the data that is relevant and related to a particular theme was grouped into appropriate and meaningful categories. Coding was then used to classify elements in text data into categories that were related to the study topic and useful for analysis (Schensul & Le Compte 2013:98). The data analysis process for this study was enhanced by referral to professional transcriber and coding specialist using the computer packages where indicated (Koshy et al 2011:128).

4.7 TRUSTWORTHINESS

Trustworthiness is the extent to which the study can be regarded as reliable and produced credible findings. Lincoln and Guba (1985) in Creswell (2013:246) suggest that credibility, transferability, authenticity, and confirmability should be demonstrated in a qualitative study. The trustworthiness and validity of qualitative studies is concerned with the truthfulness of the data collected with special emphasis on conveying the insider view and providing a detailed account of how the people we are studying understand the phenomenon (Neuman 2011:214).

Trustworthiness is the degree of confidence qualitative researchers have in their data assessing using the criteria of credibility, transferability, dependability, confirmability and authenticity (Polit & Beck 2014:323). Trustworthiness demonstrates the extent to which the study has the potential to produce credible findings and interpretation of the phenomenon under study. The test of trustworthiness can thus be described as whether or not the study investigates the proposed research questions.

All the necessary precautions were taken to ensure trustworthiness through identification and selection of appropriate informants as well as conduct of the research site visits and interviews within the research sites. Furthermore, the design and refinement of the interview guide ensured that the research questions are addressed.

The elements of credibility, confirmability, authenticity and transferability were promoted in the conduct of the study as discussed below:

4.7.1 Credibility

According to Lincoln and Guba (1985), credibility includes activities that increase the probability that credible findings will be produced. Credibility can also be enhanced by returning to the participants to assess whether they recognise the findings (Streubert & Carpenter 2011:48).

The study was undertaken over time with approval from the university's ethics committee and allowing for prolonged engagement with the participants in a familiar environment under the guidance of the supervisors who are seasoned, qualified, and experienced

researchers as mentors throughout the lifespan of research project. Cross checking of data with the participants ensured that what are reported are the views of the participants. Furthermore, the researcher underwent preparation in advanced research methodology as part of the studies for the Master's Degree in Health Studies.

4.7.2 Confirmability

Confirmability is the extent to which the research findings can be verified or confirmed by another person (Marshall & Rossman 2011:253). Polit and Beck (2014:323) submit that for confirmability to be achieved, the findings must reflect the participants' voice and the conditions of inquiry not the researcher's biases, motivations or perspectives. Confirmability was achieved by keeping an audit trail, namely the written and audio records of information collected over time, to enable other researchers to verify the findings of the conducted research. A reference list could also be beneficial in facilitating the identification of reference material used in doing the research. For this study the audio and written notes and reference materials are available for verification purposes.

4.7.3 Transferability

According to Polit and Beck (2014:323), transferability is the extent to which the research finding can be applicable to other similar situations. Qualitative researchers as indicated in Lincoln and Guba 1985:316 promote transferability through provision of rich descriptive information about the context of the studies and leave the decision of transferability to those interested in making a transfer to reach a conclusion about whether transfer can be contemplated as a possibility.

Streubert and Carpenter (2011:49) define transferability as the probability that the study findings have meaning to others in similar situations and submit that the transferability possibility rests with potential users of the findings and not the researchers.

Transferability is the level to which the results can be generalised to the population. McNiff and Whitehead (2009:13) reported that action research is about improving knowledge about existing situations each of which is unique to the people in the situation therefore action research findings cannot be generalised or applied but shared with an aim that knowledge and learning would result from the knowledge creation and sharing.

For this study the quality, credibility, confirmability, and dependability of work produced will assist in determining transferability. Transferability will be determined by the readers of the research report and not by the researcher, as in this study the purpose is to develop the framework for provision of essential medicines based on the experiences and assessment of the pharmaceutical operations within seven of the nine provinces the transferability will be up to the countries reading the report.

4.7.4 Authenticity

Authenticity is the extent to which researchers fairly and faithfully show a range of different realities. In the research report authenticity was realised when the report conveys the feeling tone of participants' lives as they are lived (Polit & Beck 2014:323).

For this study authenticity was promoted through the presentation of the findings that reflected the expressions of the participants as they knew or experienced the provision of essential medicines in their own settings making their opinions known on what strategies could be used to further enhance the provision of essential medicines

4.8 ETHICAL CONSIDERATIONS FOR THE RESEARCHER

According to Barbie (2013:32), anyone involved in social research need to be aware what is proper or improper conduct of social inquiry (research) including informed consent, voluntary participation protection from harm and confidentiality. Therefore; it is important to guard against unethical behaviour which may have an adverse effect on the participants, and reflect poorly on the profession.

In a clinical or health environment the researcher will come into contact with health professionals and their patients, possibly invading their work space, which is normally managed by authorities. Streubert and Carpenter (2011:60) present the following general ethical principles which the researcher should consider. The first is autonomy which has its roots in the categorical imperative and demands the researchers respect the rights, values and decisions of other people. The second is non maleficence which is the avoidance of intentional harm to respondents and beneficence, which stipulates that a

positive obligation to remove existing harm can be identified. Lastly, the principle of justice holds that people who are equal in relevant respects should be treated equally. The research conduct process should not cause harm to the participants and organisations, thereby supporting the principle of beneficence.

For the conduct of action research there are three applicable ethical frameworks namely personal, research and the practice itself. Emphasis is placed on the respect for the individual's autonomy, informed participation, protection from harm, data storage and utilisation (Townsend 2013:94). The researcher ensured compliance with principles of ethical research throughout the study period by implementing the measures required for conformance with the principles of autonomy, beneficence, justice and informed consent as explained below.

4.8.1 Ethical clearance

Ethical clearance for this study was obtained from the University of South Africa (Annexure A) and approval to conduct the study was obtained from the research committees of the eight Provincial Departments of Health (Annexure B) which is the permission letters from the provinces which were sites in which the research was conducted.

4.8.2 Human rights and principles of justice

Human rights include the right to self-determination, privacy, anonymity, and protection from harm. The principle of justice is concerned with fair treatment, right to privacy, and anonymity (Streubert & Carpenter 2011:65).

4.8.3 Right to self-determination (autonomy)

The prospective participants should have the opportunity to choose whether or not to participate in the study (De Vos, Strydom, Fouché & Delport 2011:116). It is accepted that as the researcher provides participants a choice to participate or not certain types would decline. For this study the potential respondents were not forced or coerced into being part of the research by being promised rewards, but did so with the full

understanding that their contribution might build knowledge for effective health services through improving essential medicine provisioning.

The participants were informed of their right to withdraw at any time or reserve their comments and inputs without being penalised.

4.8.4 Informed consent

According to Polit and Beck (2014:87), informed consent require the researcher obtain the people voluntary participation enabling the power of free choice to decline or consent voluntarily in the study after informing them of potential benefits and risks. This is done to ensure that participants have adequate information regarding the research and are capable of comprehending the information. Grove et al (2013:177) indicate that the potential participants should be informed amongst the critical points about the research purpose, methods, risks and procedures, duration of the study and the manner in which the confidentiality and privacy will be ensured.

For this study, the reasons, benefits, impact, and content of the research, as well as the criteria for being chosen were provided to the potential participants prior to commencing the study. This enabled the participants to decide whether or not to take part in the research. All participants in this study were above the consenting age of 18 years and have basic understanding of the research. The participants also received written requests to voluntarily participate in the research and signed a voluntary consent form for participation in the study on acceptance (Annexure D).

4.8.5 Privacy and confidentiality

Researchers need to consider and provide clear strategies to protect the participants' privacy and keep the information provided confidential as far as possible (Guest & Namey 2015:76). The participants' names and personal identifying information will not be used in the records. Instead symbols will be used as codes and personal details will only be accessed by the researcher and the supervisors. Should personal information be necessary for reporting purposes the permission of the affected participant will be sought.

4.8.6 Respect

The participants were not judged for their responses or experiences. All inputs were regarded as valuable; contributing to realising the purpose of the research.

4.8.7 Rights of the institution

The institutional routine and integrity should be respected during the research process (Creswell 2013:58). Integrity was maintained during the conduct of the study through proper arrangements for conducting the research site visits and interviews such that there was no interference with the participants' routine and the supervisor's permission was sought.

4.8.8 Permission to conduct research

Ethical clearance for this study was obtained from the University of South Africa and applications to the research committees of the nine provinces were submitted indicating the duration and nature of research to be conducted and was approved in writing by eight of the nine provinces prior to the commencement of the research.

4.8.9 Confidentiality

A research project guarantees the confidentiality when the researcher can identify a given person response but pledges not to divulge the personal details publicly (Barbie 2013:36).

In this study there was no direct mention of the facilities or names of any member of the health care facilities management in order to maintain the integrity, privacy, and image of the district facilities involved.

4.8.10 Integrity

The institutional routine and integrity should be respected during the research process (Creswell 2013:58). Integrity will be maintained during the conduct of the study through proper arrangements for conducting the research interviews, such as that there was no interference with the participants' routine.

4.9 SCIENTIFIC HONESTY OF THE RESEARCHER

While conducting the study the researcher should not falsify authorship, evidence, data, findings, or conclusions, and should neither plagiarise nor disclose information that will harm the participants (Creswell 2013:59).

The researcher submits that the following was complied with during the research process:

- Accurate recording and reporting of study findings.
- Reporting only the truth without distorting the acquired information to meet the needs and beliefs of the researcher.
- Acknowledged all sources ideas and processes and words used or obtained from other authors' work.
- Utilised the tested means in obtaining data and conducting the research.
- Did not coerce or manipulate participants into taking part in the research.

4.10 ENSURING RIGOR OF ACTION RESEARCH DATA

Action Research is assessed for rigor meaning criteria for the quality of research through the following validity criterions including dialogue, democracy, outcome, catalytic and process components as explained below based on Herr and Anderson (2015:67-72).

Dialogue validity

This element require that action research is conducted in a collaborative approach to ensure that the research findings resonate or make sense to the community of the practice being studied.

Democratic validity

The generation of new knowledge should demonstrate that the process was democratic and dialogue in nature enabling both the researcher and the community to engage in the execution of the research project action research will be conducted as a collaborative inquiry resulting.

Outcome validity

The research outcomes should be action oriented demonstrating that there were activities aimed at improving practice or the problem that led to the study.

Catalytic validity

The researcher and the participants must have learned something through being engaged in the research project, parties involved should experience reorientation of their reality and moved to some action to change the environment for better practice. Participants can keep a journal to record their experiences of growth during the project.

Process validity

Process validity will be ensured through triangulation of data, site visits, interview and document analysis use of multiple methods to confirm your research findings thus ensuring that research is not only based on one kind of data source.

As mentioned in the preceding pages all the necessary precautions and steps were implemented to ensure collaboration and methodology compliance and emphasis made for the improvement to be realised as well as collaboration in the execution of this study as action research project.

4.11 SIGNIFICANCE OF THE STUDY

Medicines are the second highest cost driver after the cost of employees in terms of budget allocation and expenditure. There is also high wastage of medicines due to poor stock management and expiry in the health facilities which would encourage prioritisation of improvement strategies and introduction of better mechanisms to manage medicine supply (MSH 2012:1.3).

Matsoso et al (2015:198) reported that many reports have alluded to the ineffectiveness of medicine depots in ensuring that essential medicines reach the facilities in time and in the required quantities. As such it has become imperative that attention be focused on

key issues including that of provisioning of essential medicines. The results of the National Core Standards assessment conducted in South Africa in the year 2011 reflected that all primary health clinics and community health centres were unable to meet the compliance requirements including the availability of essential medicines and supplies.

The study will therefore contribute towards design of the framework for the provision of essential medicines within the Republic of South Africa District Health Services with the intention of improving the overall availability of medicine in the various provinces which would in turn promote access to much needed treatment for the prevailing diseases affecting the population.

4.12 SCOPE AND LIMITATIONS

The study focused on the district health services which is the first level of care in the health system targeting mainly the provision of essential medicines as per the National Department of Health lists as issued in the National Core Standards as such the resultant framework will be limited to the first level of care

4.13 CONCLUSION

Conducting a study towards development of the framework for provision of essential medicines for the country contributed towards improved access to treatment and care of the population and a long healthy life for the community.

The next chapter will present the data collection and findings from the provincial site visits and interviews.

CHAPTER 5

DATA ANALYSIS, PRESENTATION, DESCRIPTION OF THE RESEARCH FINDINGS AND EFFECTS OF THE ACTION AREAS

5.1 INTRODUCTION

The research objectives for this study were:

- Explore and describe the different provinces approach in the provision of essential medicines.
- Make recommendations on a corrective measure to be implemented in order to improve the availability of medicine in the various provinces.
- Formulate a framework for the provision of essential medicines for the district health services.
- Identify best practices to be incorporated into the framework for the provision of essential medicines for the district health services.

The findings for this action research study were based on the site visits and interaction with the participants identified through purposeful sampling.

According to Savin-Baden and Major (2013:252), action research involve the following phases which were executed to arrive at the data presented below:

1. Working collaboratively with practitioners to improve practice
2. Identifying concerns and themes related to phenomenon under study
3. Prioritisation and identification of thematic concerns related to practice
4. Developing an action plan to improve practice
5. Observe the effects of action
6. Finally reflection on and evaluation of the improvement action effects

The data were collected through site visits to the seven provinces and telephonic interviews for one province due to participants' request for their organisation privacy rules purposes.

5.2 DATA MANAGEMENT AND ANALYSIS

De Vos et al (2011:333) define data analysis as the process of bringing order, structure, and meaning to the mass of collected data. It is aimed at searching for general statements about relationships among the categories of data. Data analysis involves organising the data, conducting a preliminary reading through of the database, coding and organising themes, representing the data, and forming of an interpretation thereof. These steps are interconnected and form a spiral of activities all related to the analysis and representation of the data (Creswell 2013:179).

The data for this study were recorded in writing using the interview guide (Annexure D) and also audio recorded for reference and audit trail purposes (Annexure C). The collected information was then analysed and categorised using open coding to arrive at the themes in order to identify common trends as well as unique best practices from the various contexts. The process followed in this research data analysis and presentation mirrors the steps for qualitative research data analysis and open coding namely: managing or organising the data, reading and writing memos, generating categories, themes and patterns, coding the data, testing the emergent understandings, searching for alternative explanations and representing the collected data in a report format (De Vos et al 2011:334). The qualitative data analysis facilitates non-numerical examination and interpretation of observations for the purpose of discovering underlying meanings and patterns of relationships (Barbie 2013:390).

Data analysis for this study utilised the spiral model as proposed by Creswell (2013:182-188) as follows.

5.2.1 Data organisation

The data were audio recorded and then transcribed to produce a mind map and narrative written data.

5.2.2 Reading and memoing

The transcribed data were read comprehensively to make sense of the collected facts before clustering the data in line with the research questions and the emergent themes.

5.2.3 Description, classifying and Interpretation into codes and themes

During this process the researcher compiled detailed descriptions of the experiences of the informants, highlighting the emerging themes and contrasting the collected data with the current literature and the researchers' experience and views. The outcome was coding, which entails the clustering of data into small categories of information and labelling it. Barbie (2013:402) defines coding as the classification of individual pieces of data. Coding can be categorised into three classes, namely the initial classification and labelling of concepts, axial reanalysis of the results of open coding, and selective coding which seeks to identify the central code in the study. The data were then labelled into general themes, which are broad units of information that consist of several codes aggregated to form a common idea.

5.2.4 Data interpretation

Based on the developed codes and themes the researcher made sense of data through interpretation, reflecting and contrasting the findings with the current literature available.

5.2.5 Data representation

The data were then presented in a clustered theme approach reflecting the findings and identifying trends and practices affecting medicine provisioning. The collected information was then shared with the informants for validation as a true reflection of the discussions held.

5.2.6 List of themes identified

The following themes were identified and will be discussed further in this chapter:

Essential medicines concept standardisation, role of the pharmacist in relation to the district health services scope, key processes involved in medicine provisioning, selection, procurement, rational medicine use, distribution, legal framework, management support, role of the National Department of Health, key strategies used in provisioning, special considerations, existing framework.

These themes will be discussed in the light of the participants expressed views and highlight the action areas requiring interventions to improve the provisioning of essential medicines.

5.3 DESCRIPTIVE STUDY POPULATION DATA

The study population comprised of the managers responsible for pharmaceutical services and medical depots across various provinces. The request for participation was emailed to all prospective participants followed up with a telephone call. Eight of the nine provinces in South Africa responded and accepted to participate in the study. The data was collected using the interview guide and coupled with audio recordings. One province did not respond despite numerous follow ups and emails requesting their participation on the study.

5.3.1 Participants professional profile

There were fourteen participants for this study, all of them were qualified Pharmacists nine were operating within a medical depot setting which is responsible for procurement, warehousing and distribution components and the remaining five were from the directorates of pharmaceutical services which are generally responsible for overall administration of the medicine supply management chain from the depots right to the primary health facilities as the provision of medicines is generally managed by persons trained as pharmacists as per profiles detailed below:

Table 5.1: Participants' professional profile

RESEARCH SITE	POSITION	QUALIFICATIONS	RELEVANT WORK EXPERIENCE	DISTRICT HEALTH EXPERIENCE
A 1	Depot Manager	B. Pharm	18	6
A2	Depot Responsible Pharmacist	B. Pharm	20	8
B1	Head of Pharmaceutical Services	B. Pharm	19	13
B2	Depot Manager	B. Pharm	25	6
C 1	Head of Pharmaceutical Services	B. Pharm	14	6
C2	Depot Manager	B. Pharm	21	7
D1	Pharmacy Policy Specialist	B. Pharm	02	02
D2	Depot Manager	B. Pharm	11	05
E1	Head of Pharmaceutical Services	B. Pharm	30	6
E2	Depot Manager	B. Pharm MBA	24	12
F1	Depot Manager	B. Pharm	16	12
G1	Head of Pharmaceutical Services	B. Pharm	15	8
G2	Depot Manager	B. Pharm	11	8
I2	Depot Manager	B. Pharm	10	6

5.4 PRESENTATION OF FINDINGS AND ACTION AREAS

The findings are presented below in a theme approach highlighting the common and best practices identifies in each province. The theme findings were then analysed for action areas to be addresses and considered in the development of the framework.

5.4.1 Different understanding of the essential medicine concept

WHO 2011a (2) define essential medicines are defined as those therapeutic substances used in the diagnosis, treatment, mitigation, and modification of the majority of the diseases affecting the population.

Participants defined the concept of essential medicines utilising their own situation and interpretation of the concept based on WHO definition as depicted below:

Table 5.2: Essential medicines concept

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
The basic medicine necessary in the clinics, CHC and hospitals.	The list of medications that will address the most common prevalent diseases affecting the population of South Africa.	Those medicines that cover the majority of the populations of South Africa and majority of diseases and those have been agreed upon by National.	The medicine that is used for the majority of patients for the majority illness.	Understood as defined by World Health Organization Medicines that should be available at all times required to treat majority of prevalent diseases.	Medicine that treat the majority of the diseases condition for the defined population.	Essential medicine is the medication that must be available at all times for the maintain and also prevent any disease of patients.	Essential medicines, are medicines that you can't do without, that you need to have available optimally at facility level for patients.

5.4.1.1 *Aggregate participants understanding of the concept essential medicines*

The participants from all sites explained the concept essential medicines in their own understanding however appreciated the general definition as defined by the WHO indicating a common base for the undertaking of work processes towards the provisioning of essential medicines. Essential medicine were defined from the participants view as “those medicines that covers the majority of the populations of South Africa and covers majority of diseases and those have been agreed upon by the National EML Committee and classified as such, One participant further simplified the definition of essential medicines as following:

“Basic medicines necessary in the clinics, Community Health Centres and Hospitals to treat basic ailments and should be on national tenders to ensure continuous availability”.

During the discussions all participants agreed there is no formally accepted standard to measure against the availability at all times of the essential medicines in South Africa. Not all provinces had indicators for measurement of medicine availability and provisioning provinces differed in the indicator values between 95 and 100 percent targets.

5.4.1.1.1 *Thematic action point on essential medicine concept*

There is a need of a nationally agreed standard against which to measure the availability of essential medicines as all times is not achievable across all provinces as evidenced by reported stock outs within the health facilities. There was unanimous recommendation for the National Department of Health to set benchmark against which all provinces would be assessed on the extent of acceptable provisioning and availability of essential medicines.

5.4.2 Different understanding of the role of the pharmacist in relation to the district health service scope

According to NDoH (2013:12), WHO has recognised the District Health System as the best vehicle for the implementation of primary health care and defined it in the following way “A district health system based on primary care is a more or less self-contained segment of the national health system. It comprises first and foremost a well-defined population living within a clearly delineated administrative and geographical area. It includes all the relevant health care activities in the area whether governmental or otherwise. It therefore consists of a large variety of interrelated elements that contribute to health in homes, schools, workplaces, communities, the health sector and related social and economic sectors. It includes self-care and all health care personnel and facilities whether government or non-governmental up to and including the hospital at the first referral level and the appropriate support services such as diagnostic, laboratory and logistic support. It will be most effective if coordinated by an appropriately trained health officer working to ensure as comprehensive a range as possible of promotive, preventive, curative and rehabilitative health activities.

The participants had an operational understanding of the district health system highlighting the components of the health care environment in which the frontline service delivery is offered by mostly the professional health care provider as depicted above. The participants identified their perceived role in relation to the district health services in the following manner.

Table 5.3: Participants' role within the District Health Services

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
I am responsible for the supply of medicine to all PHC, CHC and hospital in the Western region.	I am responsible for development of policies for medicine use. And putting up systems for monitoring medicine availability in the districts to ensure that the pipeline in terms of availability at depot level and also the distribution of medication from the depot to the facility level.	My responsibility is to ensure the availability of medicines within the province and the depot in particular.	We provide medicine to the whole province up until C we deliver directly to them and they order directly from us the availability of medicines lies with me to ensure we've got stock what I do is update the formulary, the provincial formulary and circulate that to facilities.	I am responsible for procurement, Warehousing and distribute medicines to Hospitals and Community Health centres.	I have to ensure consistent supply of essential medicines through implementation of efficient pharmaceutical procurement and distribution systems.	My role is overall management. I'm managing all the activities that include the procurement, distribution and development. As a manager, I have to look at all facets of provision of medicines starting from the budget, demand clinic and then procurement.	My role is to ensure optimal medicine availability to all our facilities in the province. That includes the finance aspects, it includes the procurement, it includes distribution, and the support.

5.4.2.1 Aggregate interpretation of the role of the participants within the district health system

During the discussions the district health system was understood to be limited to the district health facilities not inclusive of regional, tertiary and central hospitals. All participants whether located within urban or rural setting understood or mentioned the mobile clinic as a standing component of the district health system. The unique finding was in one province in which the district health services concept was extended to include a health post which is a location within the community which is generally manned by local volunteers remotely supported by the primary health clinic within the catchment area.

The pharmacists saw their role as cutting across “primarily district hospitals, community health centres, and clinics. So where there is a need identified by patients attending those institutions, that need is then consolidated into an order, an order for medication, and that order for medication is then presented to the depot for picking, packing, and delivery. So that’s where my role primarily comes in to ensure that the pipeline in terms of availability at depot level and also the distribution of medication from the depot to the facility level happens within a timeframe so that the five Rs are met: right quantity, right place, right time, and all the right. So that’s a big part of my role and I play an additional role also in terms of procurement from suppliers where we’ve got a procurement unit at the depot, we’ll then procure medicines on contract or sometimes on quotation basis to fill up the pipeline of available medicines at the depot. Obviously, as responsible pharmacist, I have to authorise all those purchases to ensure that the amounts being ordered are not excessive and also not too little so that we can maximise availability.”

5.4.2.2 Thematic action point on the understanding of pharmacist role within a district health services scope

There is a need to develop clear key result areas and job descriptions for standardised functioning and role of the pharmacists within the district health system to maximise their role and contribution towards improved provisioning of medicines within the district health system.

5.4.3 Common understanding of the key processes in medicine provisioning

According to MSH (2012:1.10), pharmaceutical management framework comprises four basic functions: selection, procurement, distribution, and use. Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual medicines and dosage forms and deciding which medicines will be available at each level of the health system. Procurement Includes quantifying medicine requirements, selecting procurement methods, managing tenders, establishing contract terms, and ensuring pharmaceutical quality adherence to contract terms. Distribution includes clearing customs, stock control, store management, and delivery to depots, pharmacies, and health facilities. Use includes diagnosing, prescribing, dispensing, and proper consumption by the patient. In the pharmaceutical management cycle, each major function builds on the previous function and leads logically to the next. Selection should be based on actual experience with health needs and medicine use; procurement requirements follow from selection decisions, and so forth.

At the centre of the pharmaceutical management cycle is the core of related management support systems, including the planning and organisation of services, financing and financial management, information management, and human resource management: The participants understanding was in line with the framework for pharmaceutical management.

Table 5.4: Key processes involved in medicine supply

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework	Selection, Procurement, Distribution, Rational Use, Legal Framework and Management Support in line with the Medicine Supply Framework

5.4.3.1 Aggregate Interpretation of the participants understanding of key processes involved in the provisioning of essential medicines

All participants supported the concept that the above processes are all essential in the provision of essential medicines and highlighted that these should occur in a cyclical approach with no separation of functions to avoid interruption and resultant medicine stock outs the Pharmaceutical Supply Framework as developed by Management Science for Health with the above component was unanimously accepted as the basis for the provisioning of medicines in South Africa. The understanding from all participants was that all the processes are essential to ensure consistent medicine supply and provisioning.

The majority view was that poor performance and non-execution of one or more process would result in inadequacy of medicine supply and provisioning which would be experienced as stock outs within health facilities. Across provinces, the key processes were found to be implemented differently with one province services outsourced and managed by a non-governmental organisation and other depart either operating a trading account billing facilities for the services and medicines issued or issue medicines as required for the services without taking into account whether the facility can afford or has budget for the delivery of medicines.

5.4.3.2 Thematic action point on the key processes involved in medicine provisioning

The required action is to ensure that any framework developed should encompass all key processes required for effective medicine supply management.

5.4.4 Varied approach in selection of essential medicines

The selection of the medicines depends on many factors including the prevalent diseases, treatment facilities, training and experience of the available personnel, financial resources, and population genetic demographic and environmental factors. The outcome of selection component is the essential medicines lists (EMLs) which support the systematic delivery of medicines in the health-care system (MSH 2012:16.2).

Table 5.5: Selection processes

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
All essential drugs must be on national tenders.	We have a provincial PTC, the base document we work from will be your essential drugs list or essential medicine encourage facilities to have PTCs, they encourage district PTCs to use EML as a guide.	Based on the guidelines for our PTC where there is a process.	PTC approves all medicines The NPC of National catalogue, we use that and then...then if the PPTC agrees on those motivations, then we will add it.	Essential Medicine Lists and Pharmaceutical Therapeutic Committee.	Essential Medicine Lists and Pharmaceutical Therapeutic Committee.	Selection is done by provincial PTC	Essential Medicine Lists and Pharmaceutical Therapeutic Committee.

5.4.4.1 State of functionality of the PTC as governance structure for selection of essential medicines

All provinces indicated utilisation of national essential medicine lists and pharmaceutical therapeutic committees as mechanisms for facilitating selection of medicines for use in that particular province taking into account the affordability and efficacy of the medicines. All provinces reported existence of provincial governance committee for medicines pharmaceutical therapeutics committee which is responsible for the approval of a list of medicines to be used in the particular provinces with pharmaceutical services units providing technical support .

One participant put it:

“The process in terms of the selection is based on the guidelines for our PTC where there is a process in terms of how do we select a particular drug that should be, where there is a process that outlines that it must start from downwards upwards. So at district level they will have their district PTC and such as items are they want them to be put onto the EML and then forward them to the provincial PTC. Then they are discussed at that level. Once the item is approved by the provincial PTC it's escalated to the National EML committee where it is going to be discussed based on evidence.”

However, three of the seven provinces indicated that pharmacists are also responsible to preside over the PTC meetings due to clinicians' lack of interest or non-availability to take a lead in the governance function. This practice is not supported as non-active participation of clinicians contribute to irrational medicine use and poor prescribing patterns. Further at least half of the provinces indicated limited or non-existence of district and institutional PTCs to execute an oversight role within the health facilities thus promoting upward inputs into the systems and processes of medicine selection.

5.4.4.2 Thematic action point on selection of essential medicines

There must be mechanism and systems to ensure that the pharmaceutical and therapeutic committees are functional and chaired by clinicians at all times to ensure that selection of medicines address the needs of the communities. Clear terms of reference

should be available to guide provinces on how to formulate and sustain functionality of the PTCs.

5.4.5 National contracts – procurement of essential medicine

The process of purchasing supplies utilises national, multinational, private or public suppliers, global agencies depending on availability and costs Purchasing through global agencies require that mechanisms are put in place to ensure that the quality assurance and control requirements are met to protect the service users and countries through procurement planning, purchasing inventory control traffic, receiving, incoming inspection and salvage operations (MSH 2012:18.6).

Table 5.6: Procurement processes

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
National Contracts and use quotations for those items not on contract.	There will be those who are on contract and then those who are on our non-awards where there is no contract...we will procure through the tendering process. We've strengthened DDVs.	There are different procurement models that we are using. District hospitals they order directly from us.	National Contracts and use quotations for those items not on contract.	Depot procures from pharmaceutical companies on behalf of hospitals and CHC. The hospitals in turn supplies the clinics.	National Contracts and use quotations for those items not on contract. Hospitals on using direct deliveries and depot to source medicines.	We are using national contracts. We don't have provincial contracts for those items not on tender we buy them on quotation.	National Contracts and use quotations for those items not on contract.

5.4.5.1 *Impact of national contract procurement of essential medicines*

Based on the interaction there was no single province that was solely dependent on the national contracts as not all items contracts were successfully concluded due to variety of reason including supplier capacity and uncompetitive prices and tender submissions. One participant explained:

“Then there will be those items that are on contract and then those who are on our non-awards where there’s no contract. So with the ones on contract obviously we’ll procure through the tendering process. We’ve strengthened direct delivery approach as well to improve procurement”.

There was one unique situation of an outsourced depot:

“When it comes to procurement, we procure what is on essential medicine list. We don’t procure anything outside the EML, we have a contracted service provider for all the district hospitals and clinics, but larger hospitals procure directly according to their SOP from the depot. So we have one depot that is centralised managed by a contracted service provider which manages the procurement, the warehousing and the distribution”.

All procurement for medicines was done through national tenders and dependent on tenders being available and in case of suppliers failing to deliver provinces implemented buy outs with the approval of the national department to ensure continuous stock availability. Procurement through the national contract promote cost-effectiveness through bulk purchases and price negotiations. Provinces are implementing supply chain reforms of direct delivery of medicines to health facilities rather than medicine stock being delivered via the depot first before being delivered to health facilities as an attempt to reduce delays and effective utilisation of space within the depot warehouse. One participant stated that:

“There will be those who are on contract and then those who are on our non-awards where there is no contract, we will procure through the tendering process. We have strengthened direct deliveries.”

5.4.5.2 *Thematic action point on procurement*

The procurement processes of medicines should allow for direct delivery to hospitals and community health centres to allow the depots to focus and improve procurement and supply turnaround times for the primary health clinics thus increasing the medicine availability at the lowest level.

5.4.6 Different modes for distribution of essential medicines

Distribution is meant to ensure a consistent of medicines and supplies to the facilities where they are needed whilst ensuring that resources are used in the most effective manner. Distribution system or framework has four elements which are system, information, storage and delivery elements (MSH 2012:22.2).

Table 5.7: Distribution options

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Outsourced from depot to the PHC.	Distribution is still outsourced. We have a predefined ordering and delivery schedule. The only one exception is we have Central Dispensing Unit. They then sub-distribute to different clinics.	Outsourced from depot to the District Sub Depot and hospital level. Districts have their own vehicles for distribution.	In sourced.	Distribution from depot to the hospitals and from hospitals to clinics is outsourced.	Mixed approach Hospitals, CHCs and larger PHC clinics on direct delivery using an outsourced service with a limited number of clinics receive their orders via the hospital pharmaceutical stores using facilities state pool vehicles.	Outsourced from depot to the District Depots.	Outsourced from Depot to PHC facility and Sub Depot for one Sub-district.

5.4.6.1 *Different approach in the distribution of medicines*

Distribution approach varied in all provinces with medicine stock being ordered and received by the depots in large quantities and dismantled and packed in accordance with health facilities orders. Only two provinces distributed directly from the depot to the primary health clinics.

The remaining provinces distributed to the hospitals and district depots which in turn distributed to their catchment clinics. The practice of multiple points of medicine stock delivery rather than directly to the health facilities requiring the stock has an impact on the stock turnaround times and creates an opportunity for medicine stock loss in transit. Further the distribution contract was based on varied specifications for all provinces with the five provinces being unable to confirm whether the medicines being distributed is protected from high temperature and sealed vehicles whilst in transit.

The participants presented the following arguments for outsourced distribution versus insourced distribution:

“Distribution from here we use a courier, a contracted-out courier. The main reason for that is because we reduce the risk and that’s the first reason and the second reason is we actually hand over risk on our premises to our courier and then they are responsible for the transport to the facility. The private is reliable distribution with efficient distribution. So if I was going to take internal distribution currently with our government then what is happening with their vehicles as they are not serviced regularly, they can stop on the road and you cannot have that with medicines. So you’ve got the motivation factors that you can outsource.” There was also some acceptance for an internal distribution service as explained by one participant “We’ve got the closed vans with fridge compartments in it. So it’s cooled. It’s got the air-conditioning system in it.”

5.4.6.2 *Thematic action point on distribution*

The distribution of medicines should be direct to health facilities instead of being from the depots to the hospitals or district warehouses before being sent to primary health Clinic to ensure timeous availability at the health facility level. There also should be standard

distribution contract specifications across provinces to ensure preservation of medicine quality and timeous delivery to the health facilities.

5.4.7 Rational use of essential medicine

According to WHO (2016:1), the rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

There are mechanisms and strategies to promote rational medicine use (MSH 2012:27.5) including the following:

- There must be a national multi-disciplinary structure to coordinate medicine use policies to serve as advisory structure as well as monitor the medicine use practices to promote rational medicine use.
- There must be standard treatment guidelines developed and implemented to ensure that the prescribers are guided to make sound and cost effective decision with regard to specific conditions.
- Clear mechanism for developing and revising essential medicine lists based on the treatment of choice.
- Establishment of pharmaceutical therapeutic committees in the districts and hospitals with clear responsibilities for promoting and monitoring rational use of medicines.
- Use problem based training in pharmacy therapy based on national standard treatment guidelines starting with the undergraduate levels.
- Mandatory continuous professional development for all health professionals licensing requirements to include rational medicine use content.
- Develop mechanisms to regulate prescribing patterns in the private sector through regulation and collaboration with professional societies.
- Supportive rather than punitive supervision, monitoring and evaluation mechanisms including prescription audit and feedback, peer reviews and professional syndicate groups engaging in self-identification of medicine problems and solutions in a group should promote rational medicine use.

Table 5.8: Rational medicine use

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Limited to PTC meetings and Demander forums.	<p>We are monitoring through the ABC analysis.</p> <p>The screening of the demand is something that needs to happen at district level because this has been the practice at the depot.</p>	District Pharmacist responsible for the function.	<p>The district pharmacists control the min/max of facilities depot side also min/max, on our provincial PTC is the ABC analysis that we point out if there's any irrational use.</p> <p>Promoted through capacity building in PTC sessions.</p>	Medicine Supply training for users done by District Pharmacists.	Promote compliance to National Standard Treatment Guidelines through provincially planned trainings and support.	Through PTC because it is the PTC that must ensure compliance to rational use PTC serve as a gate keeper and use of motivation for off code items.	Promoted through PTC and Demand Management Gate keeping on unusual order quantities and Items. There is also weekly stock management meeting with pharmacists from Districts and Hospitals to promote rational ordering and medicine use.

5.4.7.1 *Different approach for promotion of rational medicine Use*

As can be seen above there was varied approach to rational medicine use capacity building in some instances the pharmaceutical services units took responsibility for rational medicine use.

“We pharmaceutical services really does that and we’ve got a dedicated person who’s the driver of that they have workshops, they have training sessions, they have all sorts of activities that they do to promote rational medicine use and the engagement with the PPTC is very close as well.”

In the majority of provinces, however, lack of capacity was sighted as a reason for inconsistent rational medicine use capacity building interventions. There are no people, nobody covers that aspect.

“It is purely done by pharmaceutical services to offer support to those clinics to make sure that every clinic has got the correct stuff here, in terms of making sure that orders are done on time and done correctly and in the right quantities.”

Leave the district hospital out of it, because the responsible pharmacists at a district hospital does not see the need to be managed by district pharmacists.

“Also with us, because provincially there’s only me and the other person that is working with me is doing traditional medicine meaning that I’m alone in the whole province at the provincial level and then the other one is strictly doing cold chain, it’s not under our section also, and then there’s one for pharmacovigilance also under ARVs. So it means that I am alone for all those things and the depot’s also working with minimal staff as we are all experiencing staff shortage but we are expected to provide all the services that are requested”.

5.4.7.2 *Thematic action point on the rational medicine use*

All participants reported limited capacity building for rational medicine use. This area require improvement through development of provincial and district training schedules

and programmes targeting the health professionals in order to promote cost effective and efficient medicine provision and availability.

5.4.8 Existing legal framework

The National Drug Policy for South Africa was approved in 1996 to strengthen provision of medicines in the country and emphasised that the legal framework has to provide for establishment of the regulatory bodies with the functions of defining role of various parties, licensing, inspection and quality control, pharmaco vigilance – monitoring and management of adverse medicine reactions, advertisement and promotions, sanctions (South Africa 1996:6-7). In later developments Makhado (2014:13) reported that the medicine policy has to consist of the following components: Legislation and Regulations inclusive of country medicine control acts, establishment of statutory bodies, licensing procedures for medicines and practitioners, medicine quality control, quality assurance and trade regulations.

The participants highlighted the following as the current legal framework under which provision of essential medicine within the health system:

Table 5.9: Legal framework

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
National Drug Policy, Medicine and Related Substances Act and Pharmacy Act.	What governs us here is obviously the Medicines and Related Substances Act which governs the functions of pharmacists and the Good Warehousing and pharmacy laws, pharmacy act, medicine act, PFMA.	That is basically, the NDP...and it's your guidelines to PTC.	Definitely the pharmacy laws, pharmacy act, medicine act, PFMA National Drug Policy, Medicine and Related Substances Act and Pharmacy Act.	National Drug Policy, Medicine and Related Substances Act and Pharmacy Act.	National Drug Policy.	We've got Pharmacy Practice document, the Pharmacy Act and then we have our own provincial Standard Operating Procedures for hospitals.	National Drug Policy, Medicine and Related Substances Act and Pharmacy Act.

5.4.8.1 Common understanding of the legal framework governing provision of essential medicines

There was generally common understanding of the key legislative framework as almost all participants had indicated the National Drug Policy as well as the Medicine and Related Substances Act. One participant summarised it as following:

“The legal framework that governs us here is obviously the Medicines and Related Substances Act which governs the functions of pharmacists, the good warehousing and distribution practice and good pharmacy practice is a pharmacy council document so that’s linked to the medicine and related substances. Obviously good warehousing and distribution practice would be paramount as this piece of legal framework has more to do with the regulations that govern the Medicine Control Council, the regulator, and then obviously the Hazardous Substances Act.” The other participant reported that “we have got pharmacy practice document, the Pharmacy Act, and then we have our own provincial standard operating procedures”.

5.4.8.2 Thematic action point for legal framework

Majority of the participants submitted that The National Drug Policy which was developed in 1996 and has never been reviewed in the light of the new development including primary health care and nurse initiated anti-retroviral treatment programmes which expanded scope of nurses and prescription privileges.

There is a need to review and develop new frameworks and policies to respond to the current health sector reforms including new Nursing Act 33 of 2005 and the shortage of pharmacy personnel to manage medicine supply in the district health services in particular the primary health setting as well as the rural areas.

5.4.9 Management support

Management support systems include the following components: the planning and organisation of services, financing and financial management, information management, and human resource management. These management support systems hold the pharmaceutical management framework together (MSH 2012:38.2).

Table 5.10: Management support functions

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
<p>The province has no District Pharmacist.</p> <p>Health facilities have Pharmacy Managers posts filled partially to provide management support and guidance.</p> <p>Information management systems used include Rx Solutions and Remote Demander Modules.</p>	<p>We have what is called a Service Level Agreement which governs the relationship between the medical depot and all demanders.</p> <p>Every three months we have what we call DSM The province has district and facility pharmacists posts partially filled District Pharmacists</p>	<p>It is purely done by pharmaceutical services to offer support to those clinics to make sure that every clinic has got the correct stuff here.</p> <p>Information management systems used include Rx Solutions and Remote Demander Modules</p>	<p>We have quarterly meetings. We call it a Pharmaceutical Management forum...they monthly meetings.</p> <p>The district and facility pharmacists' posts are partially filled to provide management support</p>	<p>The district and facility pharmacists' posts are partially filled to provide management support.</p> <p>Information management systems used include Rx Solutions and Remote Demander Modules</p>	<p>Training and ensuring compliance with standards set.</p> <p>Information management systems used include Rx Solutions and in house developed medicine stock management</p>	<p>We have a dedicated person who goes to facilities to support them up to PHC level we also assisted by district pharmacists.</p> <p>We have the district pharmacist and the hospital pharmacists that are responsible for the...and the community service pharmacist</p> <p>Management support is in terms of information management, HR and finance</p> <p>The district and facility pharmacists' posts are partially filled to provide management support</p>	<p>The district and facility pharmacists' posts are partially filled to provide management support</p> <p>Information management systems used include Remote Demander Module and provincially developed medicine stock management</p>

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Pharmacy Management Demander forums exist for guidance. The unique situation is the existence of Sub-district Pharmacists.	to provide management support. Information management systems used include Rx Solutions and Remote Demander Modules		Information system used include Rx Solution as well as in house developed order management system is used.			Information management systems used include Rx Solutions and provincially developed medicine stock management.	

5.4.9.1 *Diverse management support activities for the provisioning of essential medicines*

The provinces have varied management support in terms of information management, HR, and finance for managing medicine supply in areas where there are district pharmacists there is better coordination of medicine provisioning than in those without as evidenced by higher expiry of medicines as well as poor stock management and increased stock outs.

The provinces with the district pharmacist had a challenge of having non-standardised job descriptions and blurred reporting lines with some heads of Pharmaceutical Services suggesting:

“The district pharmacists should report directly to the head of pharmaceutical services”.

Other view was:

“The district pharmacist report to the district manager as such the district managers should manage their job description and performance the district pharmacist should be responsible for the pharmaceutical services, even in the hospitals, because in that way it means myself as a head of pharmaceutical services with a district pharmacist with that professional knowledge in charge of the hospitals. So what would happen is he or she will be responsible for the whole platform and that also makes rotation or filling up of gaps even possible because you had a pharmacist but that pharmacist is not only for this hospital can be deployed anywhere there is a need within the district. So, for me, that would work because you found even just movement of medicines from the hospital to the clinics is not a problem because everybody reports to the same and they even assist in management of the district budget where you see one district is under spending, another district is overspending.”

5.4.9.2 *Thematic action point for management support*

The proposed action area on this theme is the development and standardisation of the job description of district pharmacist positions through collaboration between the heads of pharmaceutical services and district managers. Another action area is the development and implementation of a common medicine information management system in all provinces to ensure stock visibility to all decision makers to be able to maintain minimum and maximum stock levels as well as stock movement between facilities to avoid essential medicine stock outs.

5.4.10 No existing medicine provisioning framework for district health services

Table 5.11: Current provinces provisioning framework

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
No. The province have different systems and methods.	No The province has Service Level Agreements with the demanders.	No We use National Drug Policy and PTC guidelines because it gives you a guideline onto how do you procure.	No. Our Service Level Agreement is currently not signed.	No we have SOPs they just describe the process. Who will order, how regular will we order, and what if there is an order or whatever. That's the only guidance there is.	No	No we've got Pharmacy Practice document, the Pharmacy Act, and then we have our own provincial Standard Operating Procedures for hospitals.	No. We use the Medicine Control Council and Pharmacy Council rules.

5.4.10.1 None existence of the framework for provision of essential medicines for district health services

None of the sites visited indicated availability of a framework for provisioning of medicines covering the key elements of selection, procurement, distribution, rational use and management support for the district health services. The provisioning appeared to be managed generally despite the different resource and infrastructure availability between districts and hospital platforms, they indicated that their provision of essential medicines is guided by the standard operating procedures. Participants presented different inputs on the framework existence.

“We have our standard operating procedures. On our SOPs for primary health care services everything is indicated, the procedures from the depot down to the facility, how the medicine is ordered, how they can store it, and the distribution, up to the issuing to the patient”. Another participant stated the following “No, it does not cover all areas it reaches a certain portion of selection because we’ve only, I think, entered that few lines about selection but when it goes at higher level, national level, it’s not documented. It’s not reflected. It does not indicate process and we didn’t put that in”.

5.4.10.2 Thematic action area for the framework of medicine provision within the district health services

Three provinces indicated existence of service level agreement with the end users as means to guide the health facilities and clarification of roles in the provision of medicines. However, there is a need to develop a framework to guide provisioning of medicines for the district health services countrywide to promote efficiency and availability of essential medicines.

5.4.11 Approaches used in the medicine provisioning

The Pharmaceutical Management Framework adopted by the World Health Organization as developed by the Management Sciences for Health, provide broader components to promote smooth medicine provisioning. The Framework propose that medicine provisioning should be guided by selection, procurement, distribution and use components supported by the legal framework and management support across the value chain (MSH 2012:2).

Table 5.12: Provinces order handling process

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Order originate from the end user and submitted to the depot for processing.	Order originate from the end user and subjected to checking and approval by the District Pharmacist before submission for processing at the depot.	Order originate from the end user and subjected to checking and approval by the Pharmacist before submission for processing at the depot.	Order originate from the end user and subjected to checking and approval by the Pharmacist before submission for processing at the depot.	Order originate from the end user and routed through the hospital complexes for checking and approval by the Hospital Pharmacist before submission for processing at the depot.	Order originate from the end user and subjected to checking and approval by the Hospital or District Pharmacist before submission for processing at the depot.	We have an order list that has items at their level. So it doesn't allow them to order anything that is outside their level. It's standardised list.	Order originate from the end user and subjected to checking and approval by the District Pharmacist before submission for processing at the depot.

5.4.11.1 *Different order handling processes*

Provinces depending on the available human resources handle the orders differently with majority requiring a pharmacist signature of approval before the depots could process and issue the ordered medicines. This was done in order to minimise losses and inaccurate quantities as the nurses in the clinics were seen as being overstretched handling medicine ordering as additional function.

5.4.11.2 *Thematic action area in approaches for medicine provisioning*

The review of orders via a hospital pharmacist increases the turnaround times for medicine provisioning although the process does assist with the promotion of rational medicine use and prevent excess ordering. The order handling process need to be reviewed such that the order can be processed by the depots without a pharmacist analysis as long as the order is within the maximum stock level previously approved for that particular clinic.

5.4.12 *Adequacy of the provision of medicines*

MSF (2013:13) reported that lack of access to medicines has complex underlying factors ranging from health programme implementation to medicine supply system challenges. A study conducted on Pharmaceutical Management of Tuberculosis in seven of the nine provinces in the Republic of South Africa (RSA) found that the provision of essential medicines including Anti-Retroviral and Tuberculosis medication was not optimal at less than 95 percent in five of the provinces, namely the Free State, Eastern Cape, Gauteng, Limpopo, and Mpumalanga. The factors contributing to poor provisioning of medicines were especially in clinic settings poor stock control and management in nurse-led primary health clinics and a lack of pharmacist's assistants to take charge of drug supply management. Further a lack of electronic stock management systems also played a role as manual stock cards were found not to be updated at most facilities (Pure Health Consulting 2012:97). The participants generally confirmed the view that provision of medicines is better in the hospital setting than the primary health context.

Table 5.13: Adequacy of medicine provisioning

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Adequate with challenges in the PHC level due to limited pharmacy personnel, infrastructure and IT systems.	Adequate with challenges in the PHC level due to budget and space.	Adequate in the hospitals due to the whole unit that is focused on following up with suppliers. Also we have been penalising suppliers for late deliveries.	Adequate with challenges at PHC level due to the fact that the clinics battle because the sisters are busy with patients. They do not have the time to give adequate attention to the ordering of medicines.	Adequate though deliveries were delayed due to backlog and challenges with the suppliers.	Inadequate with challenges in hospitals, Community Health Centres and Primary Health Care settings due to supplies challenges, depot and facilities inefficiencies as well as manufacturing challenges	Adequate as the provisioning is outsourced and managed through a Service Level Agreement.	Adequate due to tight controls, good management, dealing with problems as they arise, and, from the depot's side, we see ourselves here as the key to the success of medicine availability at the district level.

5.4.12.1 Adequacy of the provisioning of essential medicines

Provinces reported that provisioning of medicines for the hospitals was generally adequate due to availability of pharmacists and assistants to manage ordering and stock control as well as the adequate space to store issued stock however there was unanimous presentation that primary health clinics were having inadequate medicine provisioning management as not all health districts have district pharmacists as well as Pharmacist Assistants in the primary health care facilities and poor distribution mechanism to reach the clinics. The participants highlighted the following:

“I think, ideally, we would have loved to service all the primary health care facilities that they must order through the depots because what we have looked at, the process of them ordering through sub-depots is time-consuming and, if there is a shortage of a particular item, it takes forever to resolve of that particular item unlike if they were ordering directly from the depots” also “appointment of dedicated pharmacist assistants for PHC facilities is key if the stock outs are to be minimised”.

5.4.12.2 Thematic area for action to improve adequacy of medicine provisioning

The medical depot responsible for provisioning of medicines were generally under resourced with Managers responsible in acting positions except for two provinces as such there is an urgent need to appoint permanent managers to run the medical depots. Further the vacancy rate was high with one depot operating with general workers and one pharmacist assistant. There is need to fill vacant posts with pharmacist assistants to improve efficiencies within the primary health clinics.

5.4.13 Special considerations

Table 5.14: Proposals for improving medicine provisioning

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Appointment of Pharmacist Assistants for PHC level. Electronic Stock Management System.	Adequate network and technology. Stock Management group. Transport to shift stock around. Cooperative relations between districts. Electronic Stock Management System. Centralisation of medicine budget.	Appointment of Post Basic Pharmacist Assistants for primary health care clinics for effective medicine stock management. Direct deliveries for the hospitals.	Medicine supply Management training for the health facility staff. Focal nurses responsible for stock in PHC. Electronic stock management Weekly reporting for medicine availability.	Hospital allowed to order weekly.	Invest in IT systems to support pharmaceutical procurement and distribution for visibility better stock manage stock as well as manage supply performance.	Pharmacist Assistant deployment to PHC level and Pharmacist in the hospitals to control orders. Needs forecasting to ensure consistent stock availability.	Promotion of order replenishment dependent on the IT system with minimum and maximum stock levels instead of awaiting orders from the health facilities enabling both stock control and relieve facility staff for order placement and follow up time.

5.4.13.1 Participants views on special considerations

The provinces manage the medicine budget differently either as a centralised budget enabling all facilities to have medicines as required without condition to prove financial resources or facilities have to prove budget availability with each order placed which if not produced medicine supply would be withheld with potential resultant medicine stock out in a health facility. The ideal would be central budget management with medicine provisioning based on need and budget savings shared across to fund high volume areas. Investing in electronic stock management system for medicine supply management was highly recommended to facilitate stock sharing as well as promote stock visibility and avoid excess ordering from health facilities. The participants shared good ideas on possible measures that could be implemented to enhance the provisioning of medicines. Some of the suggestions would be incorporated in the development of the proposed framework.

5.4.13.2 Thematic action area for special considerations

Whilst the employment of dedicated pharmaceutical personnel for all the primary health facilities is planned The clinics should have focal nurses responsible for medicine stock management in the facilities on condition that these nurses are exposed to medicine supply management courses in order to promote rational ordering and stock management.

5.4.14 Different strategies utilised to ensure optimum provisioning of essential medicines

Table 5.15: Best practices in medicine provisioning

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Payment of suppliers within thirty days.	Ordering schedule Direct Deliveries.	Promote Direct Deliveries for the hospitals and Community Health Centres.	Medicine Availability reporting.	Handle orders through hospital complexes due to limited human resources and capacity.	Direct Deliveries for Hospitals to improve medicine availability and direct procurement for PHC facilities.	Weekly medicines reporting.	Weekly physical stock and order review meeting between the depot, pharmaceutical services focal person, hospital and district pharmacists.
Ordering schedule Direct Deliveries.							
Maintain three months' buffer stock depot and hospital level six-week buffer stock at PHC level.	Maintain three months' buffer stock depot and hospital level six-week buffer stock at PHC level.		Depot has in-house finance unit to facilitate payment of suppliers. Dedicated medicine stock for each district within the depot warehouse.			Appointment of pharmacy personnel. Medicine Supply Management.	Dedicated Pharmacist Assistant who review orders from the facilities to identify discrepancies and irrational ordering.

5.4.14.1 *Best practices identified*

The participants emphasised the need for payment of suppliers within 30 days and maintenance of buffer stock as critical strategies to ensure consistent provisioning and minimise stock out. Depot demand management by dedicated staff was also highlighted as key to ensure that orders are checked and the companies deliver in line with the standard contract terms.

“I would say something that stands out from our depot is having our own finance unit because I hear a lot of provinces complaining that they send the payments to provincial office, to the CFO’s office, and it’s not prioritised.”

5.4.14.2 *Action area for strategies utilised to enhance medicine provisioning*

Medical depots should have dedicated finance and supply chain management units for efficient procurement and payment of suppliers.

5.4.15 Role of the National Department of Health

Table 5.16: Role of the National Department of Health

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Approve policies and standardised indicators.	Develop Stock Monitoring Systems.	Ensure timeous award of medicine supply contracts.	Provide uniform information management systems	National Tenders.	Drive implementation of improved pharmaceutical procurement models to ensure supply of medicine supplies.	Promote all stakeholders' involvement in medicine procurement.	Arrange contract timeously.
Standardise Medicine Supply Management Systems.	Provide country wide depot stock management system for global view.	Review and finalise outdate policies.	Finalise policies and norms relating to pharmaceutical management and human resources for PHC.	Monitor supplier performance.		Improve monitoring systems.	Develop and Finalise human resources standards especially for the primary health setting.
Standardise Human Resource Standards for PHC.	Contract Management for the medicine suppliers.	Introduce uniform information and human resources management systems.	Continue with supplier performance contract management.	Set Standards and policies for provision of medicines.		Develop information management systems linked at all levels.	Formalise stock transfer process across provinces.

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Ensure that all essential medicines are on national tenders to minimise buy outs.	Review and finalise policy framework.			Standardise reporting on medicine availability.		Develop and formalise norms for human resources and clinical practices.	Development and roll out of a national electronic stock management system. Standardise medicine reporting indicators.

5.4.15.1 *Multiple inputs into the role of National Department of Health*

The participants had mixed views on the role of the National Department of Health that could be categorised into human resources standards, systems, policy development and contract management.

“I think they need to come up with the proper information management systems because obviously it’s the way to go. Also primary health services are the ones that are providing majority of services and that’s where we’ve got most of the challenges. If you hear about stock-outs it will always be at clinics. Providing the tenders, definitely. They currently assist with contract management because we just don’t have the capacity to. So that is assisting a lot. I know they are working on several policies but also, I think at National level, they are also understaffed. If I look at the amount of tenders they need to secure with the small people they’ve got, I think they also hugely understaffed.”

5.4.15.2 *Thematic action area for the National Department of Health role*

Medicine provisioning practices should be standardised in the country as such National Department of Health was expected to ensure the following:

- Review, development and finalisation of the national medicine policies.
- Identification and management of reporting based on common indicators for medicine availability.
- Finalisation of human resource norms for each level of care.
- Development and roll out of the national electronic stock management system with visibility from the depot to the health facilities.

5.4.16 Specific proposals

Table 5.17: Specific proposals

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
Recruit and appoint more mid-level workers rather than professional pharmacist staff as they are difficult to retain for rural areas.	Standardise policy documents.	Review of the National Drug Policy to suit current challenges Improve rational medicine use Introduce efficient operations management to do more with less.	Depot need more HR and IT support to deliver on the mandate for provision of medicine.	Review issue based on pack size rather patient condition. Improve patient education to understand brand versus generic medicines.	None	Stock management system for real time stock management view. Uniformity.	Medicine provisioning should be linked with supply of the critical medical consumables.
Stock Visibility System roll out.	Promote Pharmaceutical Committees functionality and provide feedback.	Capacitate depots to ensure uninterrupted medicine supply.					
Push system implementation to ensure consistent medicine supply.	Appoint Pharmacists and Assistants for PHC clinics for better						

SITE A	SITE B	SITE C	SITE D	SITE E	SITE F	SITE G	SITE I
	medicine provisioning. Medicine supply Management training. Push medicine procurement strategies rather than waiting for orders from health facilities.						

5.4.16.1 *Thematic action for specific recommendations on specific proposals for improving medicine provisioning*

The importance of development and roll out of a stock visibility system and capacitation of the medical depots in terms of human resources and information management system for efficient essential medicine provisioning was mentioned by the participants as an area requiring urgent intervention. The model of pushing rather than awaiting orders from the health facilities was also recommended as a long-term strategy.

5.5 SUMMARY OF ACTION AREAS ARISING FROM THE STUDY

The following areas were identified as requiring action and intervention to improve essential medicine provisioning:

- There is a need of a nationally agreed standard against which to measure the availability of essential medicines as all times is not achievable across all provinces as evidenced by reported stock outs within the health facilities.
- The required action is to ensure that any framework developed should encompass all key processes required for effective medicine supply management
- There must be mechanism and systems to ensure that the pharmaceutical therapeutic committees are functional and chaired by clinicians at all times to ensure that selection of medicines address the needs of the communities. Clear terms of reference should be available to guide provinces on how to formulate and sustain functionality of the PTCs.
- The procurement processes of medicines should allow for direct delivery to hospitals and community health centres to allow the depots to focus and improve procurement and supply turnaround times for the primary health clinics thus increasing the medicine availability at the lowest level.
- The distribution of medicines should be direct to health facilities instead of being from the depots to the hospitals or district warehouses before being sent to primary health clinic to ensure timeous availability at the health facility level. There also should be standard distribution contract specifications across provinces to ensure preservation of medicine quality and timeous delivery to the health facilities.

- Improvement through development of provincial and district training schedules and programmes targeting the health professionals in order to promote cost effective and efficient medicine provision and availability.
- There is a need to review and develop new frameworks and policies to respond to the current health sector reforms including new Nursing Act 33 of 2005 and the shortage of pharmacy personnel to manage medicine supply in the district health services in particular the primary health setting as well as the rural areas.
- The development and standardisation of the job description of district pharmacist positions through collaboration between the heads of pharmaceutical services and district managers.
- The development and implementation of a common medicine information management system in all provinces to ensure stock visibility to all decision makers to be able to maintain minimum and maximum stock levels as well as stock movement between facilities to avoid essential medicine stock outs.
- There is a need to develop a framework to guide provisioning of medicines for the district health services countrywide to promote efficiency and availability of essential medicines.
- The order handling process need to be reviewed such that the order can be processed by the depots without a pharmacist analysis as long as the order is within the maximum stock level previously approved for that particular clinic.
- Developing standard norms for medicine management staffing in the PHC setting as well as improve the distribution mechanisms and storage areas.
- Central budget management with medicine provisioning based on need and budget savings shared across to fund high volume areas.
- Invest in electronic stock management system for medicine supply management was highly recommended to facilitate stock sharing as well as promote stock visibility and avoid excess ordering from health facilities.
- The clinics should have focal nurses responsible for medicine stock management in the facilities on condition that these nurses are exposed to medicine supply management courses in order to promote rational ordering and stock management.
- Medical depots should have dedicated finance and supply chain management units for efficient procurement and payment of suppliers.
- National depot should fast track:

- I. Review, development and finalisation of the national medicine policies.
- II. Identification and management of reporting based on common indicators for medicine availability
- III. Finalisation of human resource norms for each level of care.
- IV. Development and roll out of the national electronic stock management system with visibility from the depot to the health facilities.

5.6 CONCLUSION OF THE RESEARCH FINDINGS PHASE

The above data concludes the study findings phase, in the following paragraphs the implemented action areas to improve provisioning of essential medicines will be discussed.

5.7 DISCUSSION OF IMPLEMENTED ACTION AREAS AND EFFECTS

Action research promotes reflection by the practitioners on their practice environment and makes suggestions for improvement. Coghlan and Brannick (2010:24) defined reflection as a continuous process of identifying the problem aspects of practice, review the practice and find constructive ways to deal with the practice problem identified. Action researchers are judged on whether they reflected on what was researched, testing own judgement against the critical feedback of others thus enabling self-learning from the participants (McNiff & Whitehead 2011:14). For this study the researcher and the participants worked together to identify practice challenges through joint discussion and review of the collected data towards developing new ways of providing essential medicines for the district health services.

In the course of the study, there was engagement with various role players who could assist with the implementation of the proposed action areas. The interventions that emerged during the engagement with the participants will be discussed under the following sub headings:

5.7.1 Nationally agreed essential medicine availability standard

Based on review of the South African Department of Health strategic documents and engagement of the department of health officials there was no standard document or

guideline which provided a national benchmark standard against which to compare essential medicine availability across all the nine provinces.

The proposed intervention is for the department to consider adopting the thirty-nine items listed in the National Core Standard document for the district and community health centres measurement and the ideal clinic standard document items as basis for primary health clinic availability measurement standards.

5.7.1.1 Implemented action

The national department is currently working on the essential availability standards however; in the meantime, the department encouraged all provinces to adjust their catalogues to provide for both the national core standards and ideal clinic essential medicine standards requirements.

5.7.1.2 Implemented action effect

There is now an interim guideline against which different level of health facilities are measured against for the availability of essential medicines namely ideal clinic and national core standard lists are applicable to primary health clinics and community health centres.

5.7.2 Functionality of pharmaceutical therapeutic committees and presided by clinicians

During site visits majority of the committees were chaired and hosted by pharmacists with little involvement of clinical staff who are the prescribers of medicines in the clinical settings.

The PTC are the highest clinical governance and decision making committees in terms of provisioning of medicines as such should be functional to enhance provisioning of medicines There should be policy guidelines and terms of reference for the committees with clearly delineated mechanism and systems to ensure that the pharmaceutical therapeutic committees are functional and chaired by clinicians at all times to ensure that

selection of medicines address the needs of the communities and pharmaceutical services offices providing secretariat services and hosting function.

5.7.2.1 *Implemented action*

The participant provinces have committed to correct the structuring and functionality of the PTC by reviewing their committees' terms of reference against the draft national policy for PTC establishment.

5.7.2.2 *Implemented action effect*

There has been little progress in the structuring of the PTC as provinces had vacant posts of district pharmacists to drive the process.

5.7.3 Strengthen medical depots capacity to service primary health care clinics

The medical depots medicine distribution models differed across provinces with some depots delivering directly to all health facilities including primary health clinics and some depots delivering to the district hospitals, community health centres the sub-depots or regional depots where they exists which would then supply their catchment clinics and community health centres .This practice exposed the primary health clinics to medicine stock outs due to long route and increased turnaround times for the deliveries.

The supply system therefore has to be reviewed and human resource capacity of the depots enhanced to promote direct deliveries to the primary health clinics through activation of the demander codes to ensure that the middle man is eliminated for PHC thus increasing the medicine availability at the lowest level. Medical Depots should have dedicated finance and supply chain management units for efficient procurement and payment of suppliers.

5.7.3.1 *Implemented action*

In the course of the study three provinces were able to fill critical posts including the depot managers, finance managements and commenced with the operations review to promote better service delivery for PHC clinics.

5.7.3.2 *Implemented action effect*

There has been improvement in the provisioning of essential medicines as evidenced by reduced reports of medicine stock out across the nine provinces.

5.7.4 *Standardise the distribution services specifications across the country*

The site visits revealed that the vehicle and system used for distribution of medicines were varied across the eight provinces with few provinces utilising outsourced services with temperature control systems to maintain medicine quality standard of less than 25 degrees Celsius and prevent theft whilst others utilised standard vehicles state vehicles not custom made for distribution medicines and protection against theft. The best practice standards as stated in the good warehousing practices should be standard distribution contract specifications which ensure protection of medicines in transit against excessive temperatures, theft across provinces to ensure preservation of medicine quality and timeous delivery to the health facilities.

5.7.4.1 *Implemented action*

There are emerging trends for improvement as during the study period three provinces called for proposals for a standard distribution contract with an intention to improve the distribution of medicines as expensive and fragile health commodities. The best practice noted is that in many provinces, there is a move from using state vehicles not compliant with good warehouse management practices (GWMP) and temperature-cold chain maintenance to an outsourced approach which is generally compliant with GWMP taking into account that the department of health core strength is service delivery not necessarily the logistic management.

5.7.4.2 *Implemented action effect*

The provinces with outsourced distribution services had lesser prevalence of stock losses and delivery to health facilities generally consistent as when stock loss are reported they are recoverable and replacement of out of service vehicles becomes the responsibility of the contracted supplier.

5.7.5 Standardised medicine supply management capacity building programme

The participants also indicated varied approach to capacity building programmes to enable frontline health professionals to efficiently order and manage medicines in order to reduce wastage and irrational use of medicines.

There is an urgent need to ensure consistency through development of provincial and district training schedules and programmes targeting the health professionals in order to promote cost effective and efficient medicine provision and availability.

In order to promote rational ordering and stock management, the clinics should have focal nurses responsible for medicine stock management in the facilities and systems and support mechanisms should be in place to ensure that all nurses responsible for stock management are exposed to medicine supply management courses.

5.7.5.1 *Implemented action*

To realise this proposal, provinces were advised and accepted to solicit from the non-government organisation operating within the districts as they are funded for health system strengthening activities including capacity building on medicine supply management. All provinces have secured medicine supply management training sessions with the support of the NGOs although these training and capacity building sessions remain varied depending on the particular district challenges and resources.

5.7.5.2 *Implemented action effect*

In the course of the study nursing prescribing and medicine stock management policy was developed and approved by the National Department of Health to guide nurses prescribing and managing medicine supply as well as necessary authorisation forms circulated for completion after successful completion of the prescribed training. There was increased training for professional nurses in particular for improved stock management using the stock visibility monitoring programme and conduct of in service training by the pharmaceutical supplies organisation on the processes involved in sourcing medicines for priority condition including Tuberculosis and Vaccines.

5.7.6 Improve availability of pharmacist and pharmacist assistants at PHC level

There is a need to review and develop new frameworks and policies to respond to the current health sector reforms including new Nursing Act 33 of 2005 with revised scope of the nurses and the shortage of pharmacy personnel to manage medicine supply in the district health services in particular the primary health setting as well as the rural areas.

The participants recommended that to improve provisioning of essential medicines and good medicine stock management in the health facilities, the practice of nurses being responsible for medicine supply management as an additional function should be reviewed and concerted effort made to employ the pharmacist to coordinate medicine supply at district, sub-district and community health centres and pharmacist assistants at the primary health clinic level.

5.7.6.1 *Implemented action*

To address the shortage of pharmacists and assistants within the district health system, provinces reviewed their allocation of community service pharmacists from tertiary hospitals to the district health services as roving pharmacist checking and supporting the PHC facilities to manage the medicine supplies better as well as supervision of the pharmacist assistants. Further the National Department of Health has deployed an increased number of pharmacist assistants to the eleven National Health Insurance districts to enhance quality of medicine provisioning within the districts.

5.7.6.2 *Implemented action effect*

There are an increased number of primary health clinics within the NHI sites in the provinces with at least one pharmacist assistant contributing to better medicine stock management.

5.7.7 Standardised job description of district pharmacists

The participants during the site visits highlighted the varied understanding of the role of the district pharmacists and their reporting lines within the districts and their relationships with the pharmaceutical services at provincial levels.

Poor understanding of the role of a district pharmacist has serious consequence for service delivery as district managers are generic managers who may not necessarily have expert knowledge on managing a pharmaceutical expert in the interest of better service delivery.

5.7.7.1 *Implemented action*

The development and standardisation of the job description of district pharmacist positions through collaboration between the heads of pharmaceutical services and district managers was advocated for and following key result areas were recommended as performance agreement standard:

- Facilitate procurement of essential medicines for all health facilities within the District.
- Promote rational medicine utilisation for all the health facilities and health workers.
- Facilitate and institute mechanisms for continuous monitoring for consistent availability of essential medicines.
- Providing training in rational drug use and drug supply management.
- Supervise and mentor the mid-level workers responsible for medicine stock management.
- Conduct research on essential medicine provisioning.

- Providing professional services and advice to district management and health programmes on pharmaceutical standards and compliance.

5.7.7.2 *Implemented action effect*

The job descriptions remain varied as majority of the district pharmacists where they exist report to district management with limited input of the heads of pharmaceutical on their performance management.

5.7.8 Electronic stock management system

The participants suggested that an electronic stock management system with capability of displaying real time stock levels, able to submit orders electronically to the depots for supply and promote sharing and movement of stock across the facilities where there are stock excesses and shortages. The intention was also to ensure that ultimately health facilities would be enabled to place orders electronically thus reducing the paperwork and turnaround time for handling orders as well as improve stock management.

5.7.8.1 *Implemented action*

In order to address the recommendation, all the provinces had a stock visibility system operationalised in all the South African primary health clinics by the National Department of Health in order to promote visibility of medicine stock availability status to key role players including pharmaceutical services. However, the uptake for utilisation has been low due to limited availability of pharmacist assistants at PHC levels.

There is a further project currently in progress for the development and implementation of a common medicine information management system which is intended to link all provinces and medical depots to ensure real time medicine stock data visibility to be able to maintain minimum and maximum stock levels as well as stock movement between facilities to avoid essential medicine stock outs. Once fully implemented the system for medicine supply management would facilitate stock sharing as well as promote stock visibility and avoid excess ordering from health facilities.

5.7.8.2 *Implemented action effect*

There is now medicine stock visibility in the primary health clinic for the role players to view and activate remedial plans including follow up on order placing, delivery as well as identification of common items out of stock which could be due to poor supplier performance requiring escalation to national level. The stock visibility electronic programme is affected by network and clinic staff multiple work functions resulting in the neglect of updating the medicine availability data timeously.

5.7.9 Revised gatekeeping and processing of orders from the PHC facilities

The processing of orders from the primary health clinics was delayed by the steps involved from the clinic manager submission to the district or hospital pharmacists before the order is sent to the medical depot for processing. The orders once processed in some provinces is then returned to the hospital to deliver to the clinic which is time consuming and has potential to cause stock out at clinic level.

The proposal made was that the order handling process needs to be reviewed such that the order can be processed by the depots without having to be submitted via the district or hospital pharmacist analysis as long as the order is within the maximum stock level previously approved for that particular clinic.

5.7.9.1 *Implemented action*

The provinces had appointed pharmacist assistants and installed remote demander module for some clinics within the National Health Insurance (NHI) districts to improve medicine management, order processing and turnaround times. In the facilities where there are post basic pharmacist assistants in the clinics orders are generally submitted directly to the depots for processing using the remote demander module.

5.7.9.2 *Implemented action effect*

There is improved availability of essential medicines within the NHI districts due to increased availability of dedicated pharmacist assistants for medicine stock management and reporting.

Because the pharmacist assistants are dedicated and fully trained in medicine stock management and have capacity to move stock amongst the catchment health facilities there is reduction in surplus stock and expiry of medicines.

5.7.10 Standard staffing norms for district health services

The provinces had varied situation in their staffing norms for pharmaceutical staff composition some districts had district pharmacist and posts of Pharmacist assistants either at basic or post basic levels. Developing standard norms for medicine management staffing in the PHC setting was mentioned as a key improvement strategy.

5.7.10.1 *Implemented action*

The pharmacists were capacitated to engage with the human resource units utilising the South African Pharmacy Council good pharmacy practice standards to negotiate for minimum human resources requirement for effective pharmaceutical (medicine provisioning).

Organogram reviews are currently in process through a workload indicator staffing norms (WISN) project spearheaded by the National Department of Health including availability of at least one pharmacist assistant depending on the health facility size and patient volumes as well as national district health services structure review proposal which has made provision for district pharmacists' posts for all nine provinces.

5.7.10.2 *Implemented action effect*

In some provinces posts of the pharmacist assistants and district pharmacist have been created on the revised structure due to pharmaceutical services and programme managers lobbying human resources units for the posts creation.

5.7.11 Central budget management with medicine provisioning

The allocation and management of medicine budget was raised as a major concern as in some provinces facilities who did not have budget available could not be issued with

medicines thus resulting in the stock out owing to lack of resources and opportunity provided the pharmacist as medicine management experts manage the budget.

The participants believed that if the budget is centralised and controlled by Pharmaceutical Services there is possibility of stock movements and control of placed orders to promote efficiency through review and reduction of quantities in line with essential medicine approved lists based on need and budget savings shared across to fund high volume areas.

5.7.11.1 Implemented action

The provincial budget offices had not all agreed on budget centralisation owing to health system development and decentralisation of delegations depending on supply chain and finance management capacity of the various provinces. The compromise was that the essential medicine budget availability was officially regarded as a non-negotiable item meaning all facilities should have budget available for medicines, where shortfalls are experienced budgets adjustments are implemented.

5.7.11.2 Implemented action effect

South Africa medicine situation is improved as provinces are monitored for their capacity to meet financial obligations by settling the medicine supplier's account within 30 days. Where there are challenges fund shifts and budget adjustments are implemented.

5.7.12 Finalisation of national policies and guidelines related to essential medicine provisioning

The National Department as the policy development structure in the South African Health System had been engaged on the progress to develop the following key policies and guidelines to guide provisioning of essential medicines:

- Review, development and finalisation of the new national (drug) medicine policies taking into account the current environment and service platform changes.
- Identification and management of reporting based on common indicators for medicine availability.

- Finalisation of Human Resource norms for each level of care.
- Development and roll out of the national electronic stock management system with visibility from the depot to the health facilities.

5.7.12.1 Implemented action

The affordable medicines directorate in the course of the study was still busy with policy and guideline drafts and conceptual notes which would be consulted and shared with the relevant stakeholders before approval and implementation.

5.7.12.2 Implemented action effect

The revised draft policies and produced concept notes are awaiting discussion and clearance by the National Health Council for public comments and discussions.

5.8 CONCLUSION

The participants were encouraged to continue engaging relevant stakeholders towards realisation of the proposed interventions envisaged to promote improved provisioning of essential medicines. The next chapter will present the proposed framework for provision of essential medicines for the District Health Services.

CHAPTER 6

PROPOSED FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR THE DISTRICT HEALTH SERVICES

6.1 INTRODUCTION

The South African District Health Services is defined in line with the World Health Organization understanding of DHS as a district health system based on primary care is a more or less self-contained segment of the national health system. It comprises first and foremost a well-defined population living within a clearly delineated administrative and geographical area. It includes all the relevant health care activities in the area whether governmental or otherwise. It therefore consists of a large variety of interrelated elements that contribute to health in homes, schools, workplaces, communities, the health sector and related social and economic sectors. It includes self-care and all health care personnel and facilities whether government or non-governmental up to and including the hospital at the first referral level and the appropriate support services such as diagnostic, laboratory and logistic support. It will be most effective if coordinated by an appropriately trained health officer working to ensure as comprehensive a range as possible of promotive, preventive, curative and rehabilitative health activities (NDOH 2013:12).

The proposed framework was developed based on the input of the participants as well as adjusted based on the feedback obtained from the experts covering National Affordable Medicine (Pharmaceutical Services) Directorate and provincial district health services managers as well as Republic of South African Department of Health District Health Services Cluster in order to enhance its usefulness in practice and promote its utilization as well as possible adoption as a government framework for provision of essential medicines.

The proposed framework would cover the medicine supply management cycle components as reflected below:

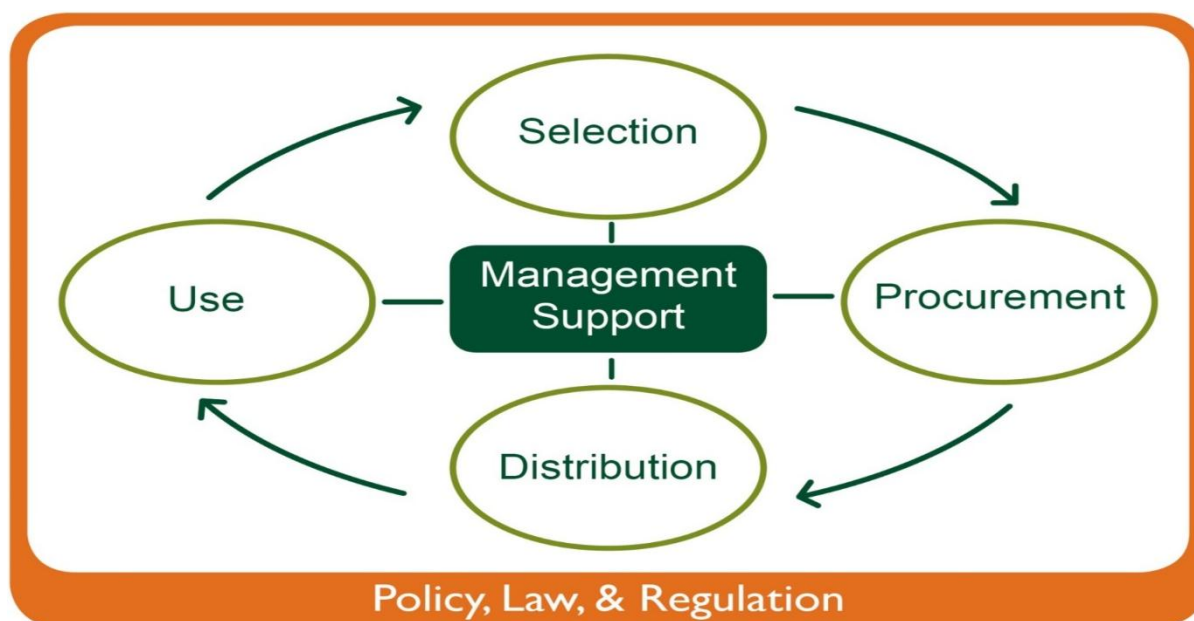


Figure 6.1 The pharmaceutical management framework
(Management Sciences for Health [MSH] 2012)

According to MSH (2012:1.10), pharmaceutical management framework comprises four basic functions: selection, procurement, distribution, and use. **Selection** involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual medicines and dosage forms and deciding which medicines will be available at each level of the health system. **Procurement** Includes quantifying medicine requirements, selecting procurement methods, managing tenders, establishing contract terms, and ensuring pharmaceutical quality adherence to contract terms. **Distribution** includes clearing customs, stock control, store management, and delivery to depots, pharmacies, and health facilities. **Use** includes diagnosing, prescribing, dispensing, and proper consumption by the patient. In the pharmaceutical management cycle, each major function builds on the previous function and leads logically to the next. Selection should be based on actual experience with health needs and medicine use; procurement requirements follow from selection decisions, and so forth.

At the centre of the pharmaceutical management cycle is the core of related management support systems, including the planning and organisation of services, financing and financial management, information management, and human resource management. These management support systems hold the pharmaceutical management framework together. Although individual parts of the framework may function independently for a

short time, the cycle as a whole will soon cease to operate and patient care will suffer without effective leadership, a functional organisational structure, adequate and sustainable financing, reliable management information, and motivated staff. The entire framework rests on a policy and legal components that establishes and supports the public commitment to essential medicine supply.

The WHO member states subscribe to the above framework to manage provision of essential medicines. The paragraphs below will discuss each component and reflect key requirements for consistent provision of essential medicines.

6.2 REPUBLIC OF SOUTH AFRICAN DISTRICT HEALTH SERVICES CONTEXT

The Republic of South Africa has nine provinces made up of 52 districts with no less than 3475 primary health clinics managed by professional nurses with limited midlevel worker staffing for the management of the medicine rooms and dispensing of medicines. The result has been long waiting times, high rate of expired medicines as well as medicine stock outs related to delayed placement of orders and follow up with the medical depots for outstanding items.

There has been attempt to improve the availability and provisioning of essential medicines through employment of Pharmacist Assistants in particular for the National health insurance districts, implementation and roll out of the stock visibility system for the reporting and monitoring of the stock levels within the primary health care platform as well as implementing other various interventions including direct delivery by suppliers to health facilities as part of service delivery improvements to ensure that the full range of essential medicines and other medical supplies are available in all public health facilities.

6.3 LEGISLATIVE AND POLICY FRAMEWORK

The following Legislative and Policy Framework have been used as basis in the formulation of the proposed framework:

- National Health Act 61 of 2003
- Pharmacy Act 50 of 1974, as amended
- Nursing Act 33 of 2005, as amended

- Medicine and Related Substances Act 101 of 1965
- National Core Standards for Health Establishments 2011
- National Drug Policy of 1996
- National Pharmaceutical and Therapeutic Committee Policy 2015
- Good Pharmacy Practice Standards 2010
- Good Warehousing Practices 2010
- Policy on Nurse Prescribing 2016

6.4 SCOPE OF THE PROPOSED FRAMEWORK

The framework will be applicable to the first level of care district health services which cover the primary health clinics up to the district office.

6.5 FRAMEWORK MISSION

Consistent availability of essential medicines.

6.6 FRAMEWORK VISION

To ensure the effective and efficient procurement, distribution, storage and use of essential medicines in order to improve health outcomes of the service users across the district health service platform.

6.7 UNDERPINNING VALUES

- Access
- Efficiency
- Quality
- Professionalism
- Collaboration

6.8 INTENDED GOALS

- Promote uninterrupted supply and provisioning of essential medicines within the district health services platform.
- Promote positive practice environment for the health professionals within the district health service.
- Promote savings and cost effective management of medicines.

6.9 STRUCTURE OF THE POLICY FRAMEWORK ON PROVISION OF ESSENTIAL MEDICINES FOR THE DISTRICT HEALTH SERVICES

The framework will be presented under the following headings:

- The selection process
- Procurement model
- Warehousing
- Distribution
- Rational medicine use
- Management support in terms of human resource development and management, information management systems

The framework will be presented in the format providing details about the component, proposed approach and the monitoring standard which could be used to assess the degree of implementation and facilitate evaluation of the framework implementation.

6.9.1 Essential medicines selection process component

The selection of medicines to be used within the district will be based on the National Essential Medicine Lists, Provincial Pharmaceutical and Therapeutic Committee Approved catalogue as well as the Ideal Clinic and National Core Standards requirements relating to provision of essential medicines.

6.9.1.1 Selection process governance

Each district shall have a district pharmaceutical therapeutic committee chaired by a senior district medical officer and comprising the minimum of the following professional members:

- Head of primary health care programmes
- Chief medical officers of the district hospitals
- District clinical specialists both medical and nursing practitioners
- Chief pharmacists of sub-districts, district hospitals and community health centres
- District pharmacist shall serve as secretariat
- Head of the health programmes within the districts
- Finance manager
- Supply chain manager
- Pharmaceutical Services Policy Specialist

The district manager shall be an ex officio member and the appointing authority for the members for period not exceeding three years which is renewable based on the participation of the particular member.

The committee shall consider requests and submissions of items to be added or removed from the platform using the prescribed analysis procedures including high cost drivers (using ABC analysis) and (VEN) vital, essential and not important category analysis.

The outcome of the committee decision on whether the items are to be added or not added in the basket of available medicines within the district health services shall be communicated to the Provincial PTC for ratification as either a provincial or a particular district item with the specific authorised prescriber level.

6.9.1.2 Framework selection monitoring standards

Number of districts with PTC meetings held at least once quarterly chaired by a senior clinician.

6.9.2 Procurement component

The medicines appearing on the essential medicine lists are generally on the national contracts arranged nationally for cost effectiveness and affordability as well as ensuring the quality of the products.

6.9.2.1 *Procurement process*

The district shall procure essential medicines through the medical depots using the prescribed forms and approved catalogues which are updated at least quarterly. The orders should be approved by the pharmacy manager for the district hospital, pharmacy supervisor for the community health centre and the district pharmacist for the primary health clinics. Orders placed in a particular financial year but not delivered by the 30th April of the new financial year shall be cancelled by the 31st May of the new year and if the items are still needed the facility shall place a new order.

6.9.2.2 *Framework procurement monitoring standards*

- At least 90 percent of items required for the ideal clinic and national core standards appearing in the approved catalogue items and available on national contracts.
- District has order cut-off date schedule for placement of orders at the depots.
- There should be service level agreement between the district and medical depot on the expected turnaround times and parties' responsibilities for smooth procurement and provisioning.

6.9.3 Good warehousing practice component

As far as possible there should be one medical depot per province warehousing medicine stock for the whole province instead of all Districts having district warehouses as the multiple depots or warehousing points increase the handling process, turnaround times for orders and the stock holding values for provinces which could lead to medicine stock out in other parts of the country. The bulk medicines shall be stored in temperature controlled rooms which should be monitored daily to ensure cold chain maintenance.

6.9.3.1 *Good warehousing practice in the health facilities*

The health facilities should have at least two rooms designated for medicine warehousing and handling, one to serve as medicine store room and the other as the dispensing room. These rooms should have temperature control mechanism to maintain the temperature below 25 degree Celsius, proper steel shelving to store the medicines and the pallets for protection of the medicines from being located directly on the floor space. The rooms should have refrigerators to store vaccine and cold chain items requiring storage between 2 and 8 degree Celsius to preserve the medicine usability.

6.9.3.2 *Good warehousing practice monitoring standard*

The number of health facilities with the medicine store room and the dispensing room with temperature control mechanism and proper steel shelving within the district.

6.9.4 Distribution component

The medicines shall be distributed by the medical depot directly to the ordering health facilities including the primary health clinics using the vehicles that are capable of maintaining the cold chain temperature at less than 25 degrees Celsius, closed design protecting the medicines from exposure to elements including sunlight and adverse weather conditions.

6.9.4.1 *Distribution approach*

The distribution of essential medicines shall be outsourced as the department of health competency is service delivery more than the logistics management. Best Practices also demonstrate that when the distribution is outsourced there is reduced risk for theft as well as losses due to inappropriate transportation of goods in the case of adverse weather conditions as well as industrial action protests which may increase turnaround times and possible state vehicles breakdown.

Distribution shall occur once a month in accordance with the delivery schedule agreed with the service users. Emergency deliveries can be considered for life threatening conditions and vaccines.

6.9.4.2 *Distribution standard monitoring*

- Number of districts with a delivery schedule with at least one delivery within the 21 working days.
- Number of districts with an outsourced distribution services for the distribution of medicines from the depot directly to the health facility.

6.9.5 Rational medicine use component

Due to limited availability of pharmacists and medical officers within the District Health System there is deviation from clinical management guidelines, limited evidence based prescriptions of antibiotics. Further the shortage of nurse clinicians as well as cold chain maintenance equipment for the vaccines and insulin and pharmacist assistants to manage stock at PHC level there is avoidable wastage of expensive medicines.

6.9.5.1 *Rational medicine*

Rational medicine use can be promoted through the following interventions:

- Medicine supply management induction for all professional nurses within the primary health setting focusing on EML and guideline compliance, ordering and stock management in line with the good pharmacy practice.
- Newly qualified professional nurses' prescription to be countersigned by the experienced primary health care nurse clinician until they are certified competent to prescribe and issue medicines after undergoing Primary Care 101 modules as required by the authorised nurse prescribing policy issued by National Department of Health.
- Conduct of prescription monthly audits for the doctors and nurses' scripts dispensed using the National Core Standards checklist tools for pharmaceutical standards and provide feedback to the clinicians.
- Promote mandatory stock count and rotation of medicines every quarter. The report should be shared with the district pharmacists and excess stock distributed to the catchment facilities to minimise expiry and excess ordering.

6.9.5.2 Rational medicines use monitoring standards

- District based medicine supply management induction for professional nurses working in PHC setting.
- Number of professional nurses who have completed Primary Care 101 and issued with Authorised Nurse Prescriber Certificate in terms of section 56 of the Nursing Act 33 of 2005.
- Number of health facilities conducting monthly prescription clinical audits using the National Core Standards tools.
- Number of health facilities within the district conducting quarterly stock count and rotation.
- Value of excess stock movement across the facilities within the catchment area.

6.9.6 Management support component

Management support comprise of activities in the areas of the planning and organisation of services, financing and financial management, information management, and human resource management (including training and capacity building).

6.9.6.1 Planning and organisation of health services

As medicines are utilised across the health services chain the planning and organisation of health services should be such that at all levels there are well trained officials charged with the responsibility of ensuring continuous provisioning and availability of essential medicines.

6.9.6.1.1 Planning and organisational requirements

The organisational structure should consist of pharmaceutical services functions and incumbents as proposed under the human resource component. The strategic plan documents and annual performance plan should include indicators measuring whether the consistent provisioning is ensured, the proposed strategic objective and indicator is the following:

Table 6.1: Proposed formula for monitoring medicine availability

Strategic objective	Indicator	Formula
Ensure consistent availability of essential medicines	Percentage availability of essential medicines as per the national core standard list for the level of care	$\frac{\text{Number of items available}}{\text{Number of items on the national core standards list}}$

6.9.6.1.2 Planning and organisation monitoring standard

The above strategic objective should appear and be monitored in all district health plans.

6.9.6.2 Finance and financial planning

The budget for provision of essential medicines has been identified as non-negotiable items for the Republic of South Africa which means that there are no financial challenges to procure medicines. The problems are mainly in payment of suppliers, excess stock and expiry of medicines due to non-execution of stock rotation and stock taking in the facilities.

6.9.6.2.1 Key financial considerations

The important areas that need to be strengthen are:

- The facilitation of timeous payment of suppliers by the districts submitting proof of deliveries to the medical depots to ensure that there is no interruption of supplies.
- Received stock orders reconciliation to be verified to ensure that medicines items and quantities ordered correspond with the received items.
- Quarterly stock rotation and redistribution to other health facilities within the district.

6.9.6.2.2 Financial monitoring standards

- Number of proof of delivery vouchers certified correct and returned to the medical depot by the health facilities.
- Number of health facilities with quarterly stock taking and rotation reports.

6.9.6.3 Human resource component

The human resource component plays a critical role in ensuring that the medicines reach the end user for better health outcomes. In practices there are different categories and varied job functions of the officers put in charge of medicine provisioning.

It is therefore important that standardised systems are put in place to ensure that the human resources are well qualified, in sufficient numbers and well developed to render cost effective provisioning of essential medicines.

6.9.6.3.1 Human resources categories and job functions for improved provisioning of essential medicines

For smooth provisioning of essential medicines, the following human resources categories with clear and standard job descriptions for consistent service delivery should be in place within a district level of care:

Table 6.2: Human resource minimum staffing for DHS

HR category	Number	Job functions	Work station
District Pharmacist – Manager	1	<ul style="list-style-type: none">• Facilitate Procurement of essential medicines for all health facilities within the• Promote rational medicine utilisation for all the health facilities and health workers• Facilitate and institute mechanisms for continuous monitoring for consistent availability of essential medicines• Providing training in rational drug use and drug supply management• Supervise and mentor the mid-level workers responsible for medicine stock management• Liase with the key stakeholders including the medical depots and pharmaceutical services	District Office

HR category	Number	Job functions	Work station
		<ul style="list-style-type: none"> Promote conduct research on essential medicine provisioning Providing professional services and advice to District Management and health programmes on pharmaceutical standards and compliance 	
Sub-district Pharmacist - Assistant Manager	1	<ul style="list-style-type: none"> Facilitate Procurement of essential medicines for all health facilities within the Sub-district Promote rational medicine utilisation for all the health facilities and health workers within the sub-district Facilitate and institute mechanisms for continuous monitoring for consistent availability of essential medicines within the sub-district Providing training in rational medicine use and medicine supply management Supervise and mentor the mid-level workers responsible for medicine stock management in the catchment health facilities Promote conduct research on essential medicine provisioning Providing professional services and advice to Sub-district Management and health programmes on pharmaceutical standards and compliance 	Sub-district Office
Pharmacy - Assistant Manager	1	<ul style="list-style-type: none"> Manage the Pharmacy and Pharmacy Store Supervise and mentor the pharmacy personnel Monitor ordering patterns and stock management practices within the hospital units Participate in rational medicine capacity building programmes Participate in the management meetings providing expert advice in relation to Pharmaceutical related matters 	District Hospital

HR category	Number	Job functions	Work station
Pharmacy Supervisor	1	<ul style="list-style-type: none"> • Manage the Pharmacy and Pharmacy Store • Supervise and mentor the pharmacy personnel • Authorise medicine orders • Monitor ordering patterns and stock management practices within the community health centre • Participate in rational medicine capacity building programmes • Participate in the management meetings providing expert advice in relation to Pharmaceutical related matters • Liase with the stakeholders including the medical depots and pharmaceutical services 	Community Health Centre
Post Basic Pharmacist Assistants	2	<ul style="list-style-type: none"> • Manage the medicine stock room within the clinic • Dispense medicine scripts from the prescribers in the clinic • Prepare, submit and follow up approved orders for facility managers with the medical depot • Participate in the Sub-district Pharmacy forum 	Primary Health Clinic-The Pharmacist Assistants shall report to the Operational Manager PHC.

6.9.6.3.2 Human resource monitoring standards

- Number of districts with the appointed district pharmacist at a manager level.
- Number of sub-districts with the appointed sub-district assistant manager pharmacy.
- Number of district hospital with the hospital pharmacy assistant manager.
- Number of community health centres with appointed pharmacy supervisor.
- Number of primary clinics with at least 2 post basic pharmacist assistants.

6.9.6.4 Training and capacity building

The modalities and treatment protocols are updated continuously as well as new employees enter the health system which necessitate orientation and induction

programmes in the health sector to promote good and safe practices in relation to medicine provisioning and supply management.

6.9.6.4.1 Annual capacity building plan

There should be an annual plan of capacity building programmes within the district to promote effective and efficient management of medicine stock covering at least the following topics and subjects:

- **Rational medicine use** covering essential medicine Lists, cost effective prescriptions.
- **Medicine supply management** covering selection, procurement, legal prescripts and warehousing components.
- **Basic pharmacist and post-basic pharmacist assistant** training to increase primary health clinic coverage with dedicated medicine room and dispensing services.

6.9.6.4.2. Training and capacity building monitoring standards

Existence of a comprehensive annual plan of capacity building programmes covering at least rational medicine use, medicine supply management and pharmacist assistant training.

6.9.6.5 Information management

The strategies used for information management include monitoring and evaluations, use of pharmaceutical management information systems and computer technology. The information systems are necessary for the reporting of medicine availability, quicker placement of orders as well as communication amongst the health professionals.

6.9.6.5.1 Required information management systems

The following systems coupled with computer hardware should be available for improved information management:

Table 6.3: Information management system options

Level	Required System	Purpose
District	Remote Demander module Stock Visibility System	To enable the district to review and approve orders electronically thus reducing turnaround times. SVS will be used to monitor stock availability within the district facilities.
Sub-district	Order management system and Remote Demander module Stock Visibility System	To assist with placement of the catchment clinic orders electronically. SVS will be used to monitor stock availability within the Sub-district facilities.
District Hospital	Order management system and Remote Demander module	To assist with placement, stock management and dispensing of medicines within the hospitals.
Community Health Centre	Order management system and Remote Demander module Stock Visibility System	To assist with placement, stock management and dispensing of medicines within the unit. SVS will be used to report stock availability within the CHC.
Primary health care clinic	Order management system and Stock Visibility System	To assist with placement, stock management and dispensing of medicines within the clinic. SVS will be used to report stock availability within the CHC.

6.9.6.5.2 Information management monitoring standard

Number of health facilities with the identified functional information system for recording, management and monitoring medicine stock.

6.10 MONITORING AND EVALUATION OF THE FRAMEWORK

The proposed framework was developed based on the input of the participants and subjected to the review of the experts covering National Affordable Medicine (Pharmaceutical Services) Directorate and provincial district health services managers as well as Republic of South African Department of Health District Health Services Cluster in order to enhance its usefulness in practice and promote its utilisation as well as possible adoption as a government framework for provision of essential medicines.

The feedback obtained from the experts' review was that the framework is useful for practice with few adjustments which were incorporated into the final proposed framework as presented in this chapter.

In practice, the framework could be monitored and evaluated by assessing the number of facilities within the district which are able to meet the proposed monitoring standards. The monitoring could be done monthly by reporting on the monitoring standards and evaluation conducted annually by reviewing the progress made in the achievement of the consistent availability and provisioning of essential medicines.

6.11 CONCLUSION

The researcher believes that if the proposed framework is implemented and supported with the necessary financial, system and human resources there will be improved provisioning and availability of essential medicines with the resultant better treatment outcomes and a long healthy life for all South Africans.

CHAPTER 7

CONCLUSION AND RECOMMENDATIONS FROM THE STUDY

7.1 INTRODUCTION

The study has been undertaken across the eight provinces of the Republic of South Africa which is a developing country with limited resources to provide for the health services coverage of all the people living in the country. The information and experiences shared have contributed towards the development of the proposed framework for improved provision of essential medicines presented in the preceding chapter.

7.2 THE RESEARCH DESIGN AND METHOD

The research design and methodology followed was qualitative research design and action research approach driven with an intention to improve clinical practice environment through:

- Exploration and description of the different provinces approaches in the provision of essential medicines.
- Proposing recommendations on a corrective measure to be implemented in order to improve the provisioning of essential medicine in the various provinces.
- Identification and sharing best practices to be incorporated into the framework for the provision of essential medicines for the district health services.
- Formulation of a framework for the provision of essential medicines for the district health services.

7.2.1 Research approach action research

This study was executed with the involvement of the participants in reviewing and improving their practice environment with an intention to promote development and consideration of new strategies to ensure consistent medicine provisioning for the health facilities.

Action research was found to be useful for this study as when participants input is sought in a collaborative manner, they share their expertise freely in an environment which utilise participatory, democratic processes to develop practical knowledge and promotion of flourishing of individuals and their communities.

7.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

During the course of the study the following findings came across as key areas to be considered in order to promote improvements in essential medicine provisioning:

7.3.1 Need for national standards for essential medicines availability

There is a need of a nationally agreed standard against which to measure the availability of essential medicines as the principle that essential medicines should be available at all times is not achievable across all provinces as evidenced by reported stock outs within the health facilities. The list comprised of limited basket of items to be measured and available in all health facilities taking into account the level of care should be developed and consulted towards a national standard for essential medicines availability.

7.3.2 Need for common framework for provision of essential medicines for the district health services

There was no province that indicated existence of a comprehensive district health services framework for provision of essential medicines. The participants expressed a need to ensure that any framework developed should encompass all key processes required for effective medicine supply management namely selection, procurement, warehousing, distribution, rational medicine use, legal framework and management support to be effective otherwise.

7.3.3 Varied functionality and composition of the pharmaceutical therapeutic committees

The study revealed that not all PTCs were functioning in the standardised approach with majority being chaired and hosted by pharmaceutical services with limited participation of clinicians as the prescribers of the medicines at the health facility level.

There must be mechanism and systems to ensure that the pharmaceutical therapeutic committees are functional and chaired by clinicians at all times to ensure that selection of medicines address the needs of the communities. Clear terms of reference should be available to guide provinces on how to formulate and sustain functionality of the PTCs.

7.3.4 The medical depots should consider the option of increasing direct deliveries for the hospitals and community health centres

In order to ensure that the medical depots capacity to service the primary health care clinics better, the participants suggested that the procurement processes of medicines should allow for direct delivery to hospitals and Community Health Centres to allow the depots to focus and improve procurement and supply turnaround times for the primary health clinics thus improving the provisioning of essential medicines at the lowest level.

7.3.5 The sub-depots are part of the bottleneck in the provisioning of medicines for the primary health clinics

The distribution of medicines should be direct to health facilities instead of being from the depots to the hospitals or district warehouses before being sent to Primary Health Clinic to ensure timeous availability at the health facility level.

7.3.6 Outsourced medicine distribution approach is better than the internal distribution

The utilisation of state vehicles which do not meet the good distribution practices and expose medicines to unsuitable temperatures, adverse weather and possible theft as well as possible irreplaceable vehicle breakdown was highlighted as a key challenge that need to be addressed to ensure consistent delivery to the health facilities.

The participants proposed that there should be standard distribution contract specifications across provinces to ensure preservation of medicine quality and timeous delivery to the health facilities and move towards outsourced distribution rather than dependency on state vehicles which are generally not capacitated to maintain and monitor cold chain in transit.

7.3.7 Standard job description for the district pharmacists

The district pharmacists were identified as a group that could strengthen implementation of the key components of the medicine supply management cycle, however, the job descriptions were generally not clear and not encompassing all the components.

The proposed framework has suggested key job functions which could be further refined with the collaboration between the heads of pharmaceutical services and district managers.

7.3.8 National Department of Health role in strengthening essential medicine provisioning

The policies governing pharmaceutical services provisioning were found to be old and outdated especially the National Drug Policy of 1996, a lot of policy changes have occurred including primary health care re-engineering and National Health Insurance which require new approaches in management of medicine supply.

The study participants highlighted a need for the National Department of Health as a policy development and coordinating unit to fast track:

- Review, development and finalisation of the national medicine policies.
- Identification and management of reporting based on common indicators for medicine availability.
- Finalisation of human resource norms for each level of care.
- Development and roll out of the national electronic stock management system with visibility from the depot to the health facilities.

7.4 STUDY RECOMMENDATIONS

The study has produced a proposed framework for the provision of essential medicines for the district health services, the recommendations will be categorised under the following headings:

7.4.1 Recommendations for National Department of Health

The National Department should consider adopting the proposed framework for the provision of essential medicines within the district health services as it has been developed with the participation of the majority of provinces (eight of the nine provinces).

The department should also facilitate the development, review and approval of policy documents and standards for the provisioning of essential medicines including the National Drug Medicine Policy as well as the standard benchmark against which provinces will be measured in terms of the availability of medicines.

7.4.2 Recommendations for Provinces

The provinces should, taking into account that the proposed framework was developed with the involvement of the pharmaceutical services managers from the majority of the provinces, consider adopting the framework as mechanism to manage medicine supply and provisioning within the first level of care.

7.4.3 Recommendations for pharmaceutical services

As the units responsible for the medicine supply management services, pharmaceutical services should work towards standardisation of human resource practices and training materials for medicine supply management across the districts within their provinces.

The harmonisation of job descriptions for the pharmaceutical management staff in collaboration with the managers responsible for district health services should be prioritised to ensure that all the key components of the medicine supply management cycle are reflected and contracted across the districts.

Further In order to promote total coverage of the primary health clinics with the deployment of pharmacist assistants, pharmaceutical services should prepare a business case highlighting the wastage of financial resources through expiry of medicines , irrational prescribing and poor storage and handling of medicine stock and strengthen relationships with programme managers especially HIV and Aids units, human resource management and chief financial officers to mobilise resources for training and eventual

appointment of the pharmacist assistants for quality medicine supply management at primary health level.

7.4.4 Recommendations for future research

Medicine provisioning is critical for the service delivery in all countries as such need to be based on proper frameworks and guidelines to promote cost effectiveness and quality health services, it is therefore recommended that health researchers conduct further studies in their own countries on the provisioning of essential medicines for district health services taking into account the pharmaceutical medicine supply management framework.

Further studies can be conducted in the Republic of South Africa to assess level of implementation of the proposed framework in provinces as well as the resource investment requirements to ensure that the framework is fully implemented in practice environment.

7.5 CONTRIBUTION OF THE STUDY

The study has reviewed and consolidated the various provinces approach in the provisioning of essential medicines and considered the best practices for incorporation into the proposed framework to guide future practice. The possibility of a standardised approach across the country's district health services platform in terms of human resource development, management and functions has potential to introduce improved management of the pharmaceutical services personnel within the district health services, cost savings and efficiency in the provision of essential medicines which is expensive health commodities.

7.6 LIMITATION OF THE STUDY

The study was conducted in eight of the nine provinces of the Republic of South Africa due to one province non willingness to participate despite numerous requests for participation.

7.8 CONCLUDING REMARKS

Consistent supply and provisioning of essential medicines which is an expensive health commodity is key in the treatment and management of prevailing diseases and require to be managed efficiently to promote uninterrupted supply to the health facilities and rational use in particular the district health services as the first level of care with limited human resource coverage.

It is believed that the experiences and proposed framework developed will go a long way in ensuring that the service users have improved access to essential medicines for control of their diseases thus increasing the life expectancy of the service users.

REFERENCES

Barber, SL, Huang, B, Santoso, B Laing, R, Paris, V & Wu, C. 2013. *The reform of the essential medicines system in china: a comprehensive approach to universal coverage*. China: Shenyang Pharmaceutical University.

From: <https://www.ncbi.nlm.nih.gov/pmc/articles> (accessed 25 July 2016).

Babar, ZU, Ibrahim, MIM, Sing, H & Bukhari, NI. 2005. *A survey of medicine prices availability, affordability and price components in Malaysia using WHO/HAI methodology*. Malaysia: University College Sedaya International.

Barbie, E. 2013. *The practice of social research*. 13th edition. United States of America: Belmont Wadsworth.

Batangan, DB & Juban, N. 2009. *Philippines pharmaceutical situation 2009 WHO health facility survey on medicines*. West Pacific Region: World Health Organization.

Bertoldi, DA, Helfer, AP, Camargo, AL, Tavares, NUL & Kanavos, P. 2012. *Is the brazilian pharmaceutical policy ensuring population access to essential medicines? Biomed Central Journal*. From: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3511298> (accessed 25 November 2016).

Bigdeli, M, Jacobs, B, Tomson, G, Laing, R, Ghaffar, A, Dujardin, B & Van Damme, W. 2012. *Access to medicines from a health system perspective*. Geneva, Switzerland: Alliance for Health Policy and System Research, World Health Organization

Bradley, H & Mogano, P. 2014. *Medicine supply management*. Cape Town: UWC.

Braun, V & Clarke, V. 2013. *Successful qualitative research*. London: Sage.

Cameroon, A, Roubos, I, Ewen, M, Mantel-Teeuwisse, AK, Leufkens, HGM & Laing, RO. 2011. Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. *Bulletin World Health Organization* (89):412-421.

Creswell, JW. 2013. *Qualitative inquiry and research design*. 3rd edition. Los Angeles: Sage.

Chinn, PL & Kramer, MK. 2011. *Integrated theory and knowledge development in nursing*. 8th edition. United States of America: Elsevier Mosby.

Coghlan, D & Brannick, T. 2010. *Doing action research in your organization*. 3rd edition. London: Sage.

Daniel, G, Tegegnenwork, H, Demissie, T & Reithinger, R. 2011. Pilot assessment of supply chains for pharmaceuticals and medical commodities for malaria, tuberculosis and HIV infection in Ethiopia. *Journal of Transactions of the Royal Society of Tropical Medicine and Hygiene* 106(1):60-62.

De Vos, AS, Strydom, H, Fouché, CD & Delport, CSL. 2011. *Research at grass roots: for the social sciences and human service professions*. 5th edition. Pretoria: Van Schaik.

Dixit, R, Vinay, T, Jayshree, T, Ubedulla, S, Manohar, VS & Chandrasekhar, N. 2011. Availability of essential medicines: A primary health care perspective. *Indian Journal of Pharmacology* 43(5):599-600.

Engelbeen, B & Makhado, M. 2014. *Medicine supply management winter school*. Cape Town: UWC.

Elamin, IE, Ibrahim, MIM & Yousif, MIM. 2010. Availability of essential medicines in Sudan. *Sudanese Journal of Public Health* 5(1):32-37.

Gray, A. 2014. Medicine shortages—unpicking the evidence from a year in South Africa. *Australasian Medical Journal* 7(5):208-212.

From: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4051355/pdf> (accessed 21 July 2015).

Gray, A & Manasse, HR (Jr). 2012. Shortages of medicines: a complex global challenge. Geneva. *Bulletin of the World Health Organization* 90(3)158-158.

Gray, A, Vawda, Y & Jack, C. 2011. *South African health review*. Durban: Health System Trust.

GCIS. 2010. *Delivery agreement for outcome 2: A long and healthy life for all South Africans*. Pretoria: Government Printers.

Grove, SK, Burns, N & Gray, JR. 2013. *The practice of nursing research appraisal, synthesis and generation of evidence*. 7th edition. China: Elsevier Saunders.

Guest, G & Namey, E (eds). 2015. *Public health research methods*. United Kingdom: Sage.

Grbich, C. 2013. *Qualitative data analysis: an introduction*. 2nd edition. London: Sage.

Harding, J. 2013. *Qualitative data analysis: from start to finish*. Los Angeles: Sage.

Health 24. 2010. Drug shortages in South Africa. From: <http://www.health24.com/news/Healthcare/1-918,56153.asp> (accessed 12 May 2015).

Health Systems Trust. 2013. *National health facilities baseline audit 2011 national summary report*. Durban: Health Systems Trust.

Herr, K & Anderson, GL. 2015. *The action research dissertation: a guide for students and faculty*. United States of America: Sage.

International Council of Nurses. 2011. *Closing the gap increasing access and equity*. Switzerland: ICN.

Kangwana, BB, Njogu, J, Wasunna, B, Kedenge, SV, Memusi, DN, Goodman, CA, Zurovac, D & Snow, RW. 2009. Short report: malaria drug shortages in Kenya: A major failure to provide access to effective treatment. *American Journal of Tropical Medicine and Hygiene* 80(5):737-738.

Kheirandish, M, Rashidian, A, Kebriaeezade, A, Majid, A, Cheraghali, MA, Soleymani, F. 2015. Review of pharmaceutical policies in response to economic crises and sanctions. Iran. *Journal of Research in Pharmacy Practice*. From: <https://www.ncbi.nlm.nih.gov/pmc/articles> (accessed 25 July 2016).

Kotwani, A, Ewen, M, Dey, D, Lyer, I, Lakshmi, PK., Patel, A, Raman, K, Singhai, GL, Thawani, V, Tripathi, S & Laing, R. 2009. Prices and availability of common medicines at six sites in India using standard methodology. *Indian Journal of Medicine Research* 127:645-654.

Koshy, E, Koshy, V & Waterman, H. 2011. *Action research in healthcare*. London: Sage.

Larkin, H. 2011. Drug shortages may be worst. *Hospital Health Network* 85(2):28-30, 32.

Lubinga, SJ, Larsen-Cooper, E, Crawford, J, Matemba, C, Stergachis, A & Babigumira, JB. 2014. *Impact of pharmacy worker training and deployment on access to essential medicines and health outcomes in Malawi: protocol for a cluster quasi-experimental evaluation*. Biomed Central: Washington.

Lufesi, NN, Andrew & Aursnes, I. 2007. Deficient supplies of drugs for life threatening diseases in an African community. *BMC Health Services Research* 7(86):1-7.

Lu, YE. 2006. *A survey of medicine prices, availability and affordability in Shanghai, China using the WHO/HAI methodology*. Department of Health Economics, School of Public Health Fudan University Shanghai, PR China.

Makhado, M. 2014. *Medicine supply management winter school*. Cape Town: UWC.

Management Sciences for Health (MSH). 2012. *Managing drug supply*. New York: Kumari Press.

Marshall, C & Rossman, GB. 2011. *Designing qualitative research*. 5th edition. California: SAGE.

Matsoso, MP, Fryatt, RJ, & Andrews, G (eds). 2015. *The South African health reform: moving towards universal coverage*. Cape Town: Juta.

McNiff, J & Whitehead, J. 2011. *All you need to know about action research*. 2nd edition. Los Angeles: Sage.

McNiff, J. & Whitehead, J. 2009. *Doing and writing action research*. 2nd edition. Los Angeles: Sage.

Medicines Sans Frontiers (MSF). 2013. *Treatment Action Campaign, Section 27 and Rural Health Advocacy Project. Emergency intervention at Mthatha depot: The hidden cost of inaction: Mthatha*. Eastern Cape: Republic of South Africa.

Morse, JM. 2012. *Qualitative health research: creating a new discipline*. United States of America: Left Coast Press.

Nash, K. 2012. *In short supply*. United States of America: Dermatology Times.

National Department of Health (Republic). South Africa. 2015. *National policy for the establishment and functioning of pharmaceutical and therapeutics committees in South Africa*. Pretoria: Government Printers.

National Department of Health (Republic). South Africa. 2013. *District health system policy framework and strategy 2014-2019*. Pretoria: Government Printers.

National Department of Health (Republic). South Africa. 2012a. *Non negotiables for public health sector*. Pretoria: Government Printers.

National Department of Health (Republic). South Africa. 2011a. *Annual report 2010/2011*. Pretoria: Government Printers.

National Department of Health (Republic). South Africa. 2011b. *National core standards for health establishments in South Africa*. Pretoria: Government Printers.

National Department of Health (Republic). South Africa. 2009a. *Strategic plan 2009-2014*. Pretoria: Government Printers.

National Department of Health (Republic) South Africa. 2009b. *Health programme of action*. Pretoria: Government Printers.

Neuman, WL. 2011. *Social research methods: qualitative and quantitative approaches*. 7th edition. Boston: Alyn and Bacon.

Ohuabunnwa, MSI. 2010. *The challenges of making quality essential drugs and supply available for PHC services in Nigeria*. World Health Organization Publication. From: <http://apps.who.int/medicinedocs/documents/s18398en/> (accessed 13 June 2015).

Padarath, A & English, R (eds.). 2013. *South African health review 2012/13*. Durban: Health Systems Trust.

Patel, A, Norris, P, Gauld, R & Rades, T. 2008. *Quality in South Africa: Perceptions of key players involved in medicines distribution*. University, New Zealand: Dunedin.

Polit, D & Beck, CT. 2014. *Essentials of nursing research: appraising evidence of nursing practice*. 8th edition. China: Lippincott Williams & Wilkins.

Public Service Commission. 2011. *Citizens talk: A citizen satisfaction survey report*. Johannesburg: South Africa.

Pure Health Consulting. 2012. *Pharmaceutical management of TB in South Africa; rapid assessment conducted in 7 provinces*. Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Reason, P & Bradbury, H (eds). 2011. *The handbook of action research*. 2nd edition. London: Sage.

Sabih, F, Bile, KM, Buehler, W, Hafeez, A, Nishtar, S & Siddiqi, S. 2010. Implementing the district health system in the framework of primary health care in Pakistan: Can the evolving reforms enhance the pace towards the millennium development goals. *Eastern Meditterian Health Journal* 16. From:

<http://www.sanianishtar.info/pdfs/Implementingthedistricthealthsystem.pdf> (accessed 28 November 2016)

Savin-Baden, M & Major, CH. 2013. *Qualitative research: The essential guide to theory and practice*. Oxon: Routledge.

Shafiq, Y, Shaik, BT & Kumar, R. 2011. Availability and affordability of essential medicines: exploring the health seeking behaviours and health service utilization for children under-5 years living in squatter settlement of Karachi, Pakistan. *J Ayub Med Coll Abbottabad* 23(1):132-138. From:

<https://www.ncbi.nlm.nih.gov/pubmed/22830168> (accessed 26 November 2016).

Schensul, JJ & Le Compte, MD. 2013. *Essential ethnographic data collection methods: a mixed methods approach*. United States of America: Altamira Press.

SECTION 27. 2013. *Monitoring our health: an analysis of the breakdown of healthcare services in selected Gauteng facilities*. South Africa: SECTION 27.

South Africa. 2005. *Nursing Act, no 33 of 2005, as amended*. Pretoria: Government Printers.

South Africa. 2003. *National Health Act, no 61 of 2003*. Pretoria: Government Printers.

South Africa. 2002. *Medicine and related substances Act, no 101 of 1965, as amended*. Pretoria: Government Printers.

South Africa. 1996. *National drug policy*. Pretoria: Government Printers.

South African Pharmacy Council. 2010. *Good pharmacy practice in South Africa*. 4th edition. Arcadia: SAPC.

Stock Out. 2016. *2015 Stock Outs National Survey. Third Annual Report – South Africa*. Johannesburg: Stop Stock Out.

Strengthening Pharmaceutical Systems. 2009. *Report on the state of availability and delivery of pharmaceuticals in the Northern Cape Province*. Pretoria: Strengthening Pharmaceutical Systems/Management Sciences for Health.

Streubert, HJ & Carpenter, DR. 2011. *Qualitative research in nursing-advancing the humanistic imperative*. 5th edition. Philadelphia: Lippincott Williams and Wilkins.

Taylor, B & Francis, K. 2013. *Qualitative research in the health sciences: Methodologies, methods and processes*. United States of America: Routledge.

Thom, A & Langa, L. 2010. *National medicine shortages*. The Star, 12 April:7.

Thompson, S & Ogbe, E. 2012. *Helpdesk report: Availability of essential medicines*. United Kingdom: DFID.

Townsend, A. 2013. *Action research: The challenges and understanding and changing practice*. England: Open University Press.

Tumwine, Y, Kutyabami, P. Odoi, RA. & Kalyango, JN. 2010. Availability and expiry of essential medicines and supplies during the 'pull' and 'push' drug acquisition systems in a rural Ugandan Hospital. *Tropical Journal of Pharmaceutical Research* 9(6):557-564.

United Nations. 2016. *Sustainable development goals: 17 goals to transform our world*. Geneva: United Nations.

Wangu, MM & Osuga, BO. 2014. Availability of essential medicines in public hospitals: a study of selected hospitals in Nakuru county Kenya. Kenya: *African Journal of Pharmacology*. From: <http://www.academicjournals.org/article/article1398866137> (accessed 23 November 2016).

Wirtz, VJ. Russo, G & Escobar, ML. 2009. Access to medicines by ambulatory health service users in Mexico: an analysis of the national health surveys 1994 to 2006. *Salud Publica Mex* 52:30-38.

WHOAFRICA. 2006. *Final report regional workshop on improving procurement and supply management systems in the African region*, Brazzaville, Congo 2006 June 20-23.

World Health Organization. 2016. *Essential medicines*. Geneva: WHO.

World Health Organization. 2015. *World country profiles*. Geneva: WHO.

World Health Organization. 2014. *Essential medicines and health products Biennial Report 2012–2013*. Geneva: WHO.

World Health Organization. 2011a. *World medicine situation 2011: Medicine prices, availability and affordability*. Geneva: WHO.

World Health Organization. 2011b. *Discussion paper essential medicine for non-communicable diseases*. Geneva: WHO.

World Health Organization. 2010. *Fact Sheet No 325 on essential medicines*. From: <http://www.who.int/mediacentre/factsheets/fs325/en/> (accessed 25 June 2015).

Van Der Walt, C. 2014. *Medicine supply management lecture*. Cape Town: UCT.

Yang, H, Dib, HH, Zhu, M, Gang, Q & Zhang, X. 2010. Prices, availability and affordability of essential medicines in rural areas of Hubei province, China. *Health Policy and Planning* 25:219-229.

Zimbabwe. 2011. *Country pharmaceutical profile*. Harare, Zimbabwe: Government Printers.

Zuma, SM. 2013. Factors contributing to non-availability of essential medicines within the Free State district health service province. Unpublished Masters Dissertation. Pretoria: University of South Africa.

ANNEXURES

**ANNEXURE A: ETHICAL CLEARANCE CERTIFICATE: HEALTH
STUDIES HIGHER DEGREES COMMITTEE, UNISA**



**UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE**

REC-012714-039

HS HDC/370/2014

Date: 10 December 2014 Student No: 3408-626-9

Project Title: Framework for provision of essential medicines for district health services.

Researcher: Sibusiso Memory Zuma

Degree: D Litt et Phil Code: DPCHS04

Supervisor: Prof LM Modiba

Qualification: D Cur

Joint Supervisor: -

DECISION OF COMMITTEE

Approved



Conditionally Approved



for **Prof L Roets**
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

L.L. Roets (Prop)

Prof MM Moleki

Prof MM Moleki
ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

ANNEXURE B: APPROVAL TO CONDUCT THE STUDY FROM THE RESEARCH COMMITTEES OF THE EIGHT PROVINCIAL DEPARTMENTS OF HEALTH



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM63/15
Enquiries : Ms G Khumalo
Telephone : 033 – 395 3189

Dear Mr S M Zuma

Subject: Approval of a Research Proposal

1. The research proposal titled 'FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR DISTRICT HEALTH SERVICES' was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

The proposal is hereby **approved** for research to be undertaken at KwaZulu-Natal Department of Health.

2. You are requested to take note of the following:
 - a. **Make the necessary arrangement with the identified facility before commencing with your research project.**
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee

Date: 31/03/15

uMnyango Wezempilo. Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

OUTCOME OF PROVINCIAL PROTOCOL REVIEW COMMITTEE (PPRC)

Researcher's Name (Principal investigator)	Sibusiso Zuma
Organization / Institution	UNISA
Research Title	Framework For Provision Of Essential Medicines
Contact number	Address: N/A Contact no: N/A Cell: 083 444 5205 Email: zumasibusiso@yahoo.com
Protocol number	GP 2015RP55 261
Date submitted	09/03/2015
Date reviewed	March 2015
Outcome	APPROVED
Date resubmitted	N/A
Date of second review	N/A
Final outcome	APPROVED

It is a pleasure to inform that the Gauteng Health Department has approved your research on "Protocol Title: Framework for Provision of Essential Medicines. The Provincial Protocol Review Committee kindly requests that you to submit a report after completion of your study and present your findings to the Gauteng Health Department.

Recommended

Dr B. Kalafeng (on behalf of PPRC)

Date

31/03/2015

Approves / not approves

Dr R. Lethebe
Acting DDG: Clinical Services

Date

22/03/15



Department of Health
Mpumalanga Provincial Government

Building No. 3, No. 7 Government Boulevard, Riverside Park Extension 2, Mbombela, 1200, Mpumalanga
Private Bag X 11285, Mbombela 1200, Tel: 013 766 3429, int: +27 13 766 3429, Fax: 013 766 3459, int: +27 13 766 3459

Litiko Letemphilo

Umnnyango WezaMaphilo

Departement van Gesondheid

Enquiries: Themba Mulungo (013) 766 3511

02 July 2015

Mr. Sbusiso Zuma
105 Queens Road
King Williams Town

Dear Mr. Sbusiso Zuma

**APPLICATION FOR RESEARCH & ETHICS APPROVAL: FRAMEWORK FOR PROVISION
OF ESSENTIAL MEDICINES FOR DISTRICT HEALTH SERVICES**

The Provincial Health Research and Ethics Committee has approved your research proposal in the latest format that you sent.

PHREC REF: MP_2015RP18_577

Kindly ensure that you provide us with the soft and hard copies of the report once your research project has been completed.

Kind regards

MR. MOLEFE MACHABA
RESEARCH AND EPIDEMIOLOGY

02/07/2015
DATE





Eastern Cape Department of Health

Enquiries: Zonwabele Merile
Date: 27th March 2015
e-mail address: zonwabele.merile@impilo.ecprov.gov.za

Tel No: 040 608 0830
Fax No: 043 642 1409

Dear Mr SM Zuma

Re: Framework for provision of essential medicines for district health services (EC_2015RP17_20)

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE



Ikamva eliqaqambileyo!



health

Department of
Health
FREE STATE PROVINCE

4 April 2015

Mr Sibusiso Memory Zuma
105 Queens road
King Williams Town

Dear Mr Sibusiso Memory Zuma

Subject: Framework for provision of essential medicines for district health services

The above mentioned correspondence bears reference.

- Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participant must be obtained.
- Ascertain that your data collection exercise neither interferes with the day to day running of the health facilities nor the performance of duties by the respondents.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study.
- Confidentiality of information will be ensured and no names will be used.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of South Africa and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of South Africa and to Free State Department of Health.
- Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Approval should be submitted to khusemj@fshealth.gov.za or sebeclats@fshealth.gov.za before you commence with the study
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see <http://nhrd.hst.org.za>

Trust you find the above in order.

Kind Regards

Dr D Motau

HEAD: HEALTH

Date: 11/04/2015

Head : Health

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Navrae :

Date : 28 January 2016
Letlha :
Umhla :
Datum :

Reference :
Tshupelo : Tel: 053 830 2122
Isalathiso : Fax: 086 541 7122
Verwysings :

Mr. Sibusiso Memory Zuma
105 Queens Road
KWT
5600

Dear Mr. SM Zuma

PROJECT TITLE: FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR DISTRICT HEALTH SERVICES

Reference Number: NC_2015RP28_571

The application to conduct the study was received and has been reviewed by the Provincial Health Research and Ethics Committee (PHREC)

Approval is hereby granted to conduct the above-mentioned study in the Northern Cape Province

Please note: This approval is valid for a period of one year from the date of approval.

The following conditions have to be noted:

1. The study should be conducted at **no** cost to the Northern Cape Department of Health
2. The approval is limited to the research proposal as submitted in the application.
3. Variation or modification on the research must be notified formally to PHREC for further consideration.
4. The PHREC may monitor the project at any time.
5. A six months progress report **must** be submitted to the PHREC



We are committed to achieving our vision through a decentralized, accountable, accessible and constantly improving health care system within available resources. Our caring, multi-skilled, effective personnel will use evidence-based, informative health care and maturing partnerships for the benefit of our clients and patients.

6. At the completion of your study a copy of the final report must be submitted to the Research and Development Directorate.
7. The Northern Cape Senior Management Committee will be briefed on the outcome of the study prior to publishing.

Furthermore, after the completion of your project, you may be requested to do a presentation on the final findings of your study.

The committee wishes you success on your study

Yours Faithfully



Dr. Eshetu Worku
Chairperson: PHREC
E-mail: eworku@ncpg.gov.za
Tel: 053 830 2122
Fax: 086 541 7122

28/01/2016
Date



health

Department of
Health
North West Province
REPUBLIC OF SOUTH AFRICA

3801 First Street
New Office Park
MAHIKENG, 2735

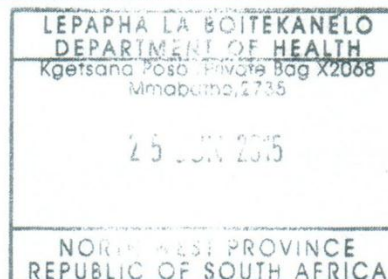
Enq: Keitumetse Shogwe
Tel: 018 391 4504
kshogwe@nwpg.gov.za
www.nwhealth.gov.za



POLICY, PLANNING, RESEARCH, MONITORING AND EVALUATION

Name of researcher : S.M Zuma
University of South Africa

Physical Address _____
(Work/ Institution) _____



Subject : Research Approval Letter- Framework for the provision of essential medicines in the South African District Health Services.

This letter serves to inform the Researcher that permission to undertake the above mentioned study has been granted by the North West Department of Health. The Researcher is expected to arrange in advance with the chosen facilities, and issue this letter as proof that permission has been granted by the Provincial office.

This letter of permission should be signed and a copy returned to the department. By signing, the Researcher agrees, binds him/herself and undertakes to furnish the Department with an electronic copy of the final research report. Alternatively, the Researcher can also provide the Department with electronic summary highlighting recommendations that will assist the department in its planning to improve some of its services where possible. Through this the Researcher will not only contribute to the academic body of knowledge but also contributes towards the bettering of health care services and thus the overall health of citizens in the North West Province.

Kindest regards


Dr. FRM Reichel
Director: PPRM&E

24/06/2015
Date

Researcher

Date



Healthy Living for All



REFERENCE: WC_2015RP21_175
ENQUIRIES: Ms Charlene Roderick

University of South Africa

Jean Simonis Street

Cape Town

7500

For attention: Mr Sibusiso Zuma

Re: Framework For Provision of Essential Medicines for District Health Services.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact following people to assist you with any further enquiries in accessing the following sites:

Pharmaceutical Services

Helen Hayes

021 483 4567

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion date* which was submitted, researchers are expected to complete and submit a progress report

(Annexure 8) to the provincial Research Co-ordinator

(Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely



Dr A Hawkridge

DR A HAWKRIDGE

DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE:

2/11/2016.

ANNEXURE C: EXCEPT FROM THE TRANSCRIPTION RECORDS

I Now, we doing the responsible pharmacist for Free State medical depot. So we're starting. Thank you for seeing me. in summary, just tell me what is your job position, qualification, number of experience.

P4 I am presently a responsible pharmacist at the provincial medical depot. I've been appointed since first of February two thousand and fifteen. I've been appointed in that position. I'm a pharmacist qualified in end of nineteen eighty-seven so I've got roughly about twenty-five years' experience in pharmacy, B Pharm, in various fields of pharmacy, primarily in...eighty percent of that would be in hospital pharmacy and then about roughly six years' experience in warehousing or distribution pharmacy.

I What has been your experience in terms of district health services?

P4 District health services, I spent a year in the Northern Cape as a district pharmacist and then, like I say, the six years' experience in warehousing

I Which includes?

P4 That includes supporting the district health system in terms of availability of medicines and so on.

I Now, what's your understanding of your role in the provision of medicine in district health services in the province, you've got thirty-one hospitals. Then you've got two thirty-two PHC. So what role do you play in the provision of medicines for the DHS?

P4 For the district health. Obviously, within the medical depot setup, because the medical depot in the Province provides a service of making medicines available on order to a number of institutions at various levels of care. Now, as you mentioned, primarily district hospitals, community health centres, and clinics. So where there is a need identified by patients attending those institutions, that need is then consolidated into an order, an order for medication, and that order for medication is then presented to the depot for picking, packing, and delivery. So that's where my role primarily comes in to ensure that the pipeline in terms of availability at depot level and also the distribution of medication from the depot to the facility level happens within a timeframe so that the five Rs are met: right quantity, right place, right time, and all the right. So that's a big part of my role and I play an additional role also in terms of procurement from suppliers where we've got a procurement unit at the depot, we'll then procure medicines on contract or sometimes on quotation basis to fill up the pipeline of available medicines at the depot. Obviously, as responsible pharmacist, I have to authorise all those purchases to ensure that the amounts being ordered are not excessive and also not too little so that we can maximise availability. So in rough, that's my role.

**INTERVIEW AND SITE VISIT
GUIDE FOR THE STUDY ON THE
FRAMEWORK FOR THE
PROVISION OF ESSENTIAL
MEDICINES FOR THE HEALTH
SERVICES**

SECTION A: INFORMATION TO PARTICIPANTS AND CONSENT FORM

Thank you for agreeing to be the participant in this study.

The study intends to explore and produce a framework for the provision of essential medicines for the District Health Services using action research approach.

You have been selected as a participant for this study on the basis of your expertise and involvement in the provision of medicines within the district health services.

The data collected during the site visits and interview will form the basis for the Thesis of the Doctor of Philosophy and Literature Health Studies Degree with UNISA.

PROCEEDINGS DETAILS

The site visits and the interview sessions will not exceed 10 days for the whole study period per site with a view to learn and share best practices for sustained improvements.

The site visits and interview will be conducted by the researcher with the proceedings being audio recorded.

Participants will be allowed to ask any questions if there is any point you would like to be clarified during this process.

The results will be shared with yourselves once completed for verification purposes.

There shall not be any reference to your personal information, and each informant is free to withdraw or not comment if not comfortable.

You are requested to sign the attached consent form if you are voluntarily willing to be a participant for the study.

**CONSENT FORM TO BE A PARTICIPANT IN THE RESEARCH FOR THE
FRAMEWORK FOR PROVISION OF ESSENTIAL MEDICINES FOR DISTRICT
HEALTH SERVICES**

I hereby voluntarily consent to participate in the
study for the framework for provision of essential medicines for the District Health
Services

PARTICIPANT'S SIGNATURE

FULL NAMES

CONTACT NUMBERS

DATE

SIGNATURE OF THE RESEARCHER

MR SM ZUMA

DATE

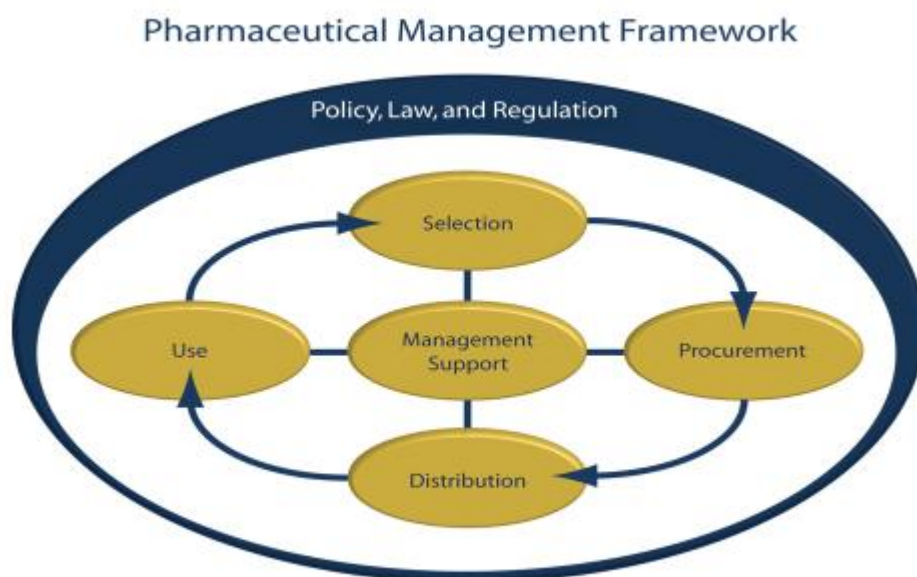
SECTION B: BACKGROUND OF PARTICIPANTS

We would like to know a bit more about you as a person

- Please introduce yourself in terms of job position, qualifications and number of years' experience in the provision of essential medicines for district health services.

SECTION C: ASPECTS REGARDING PROVISION OF ESSENTIAL

- Please explain your role in the provision of medicines in relation to the district health services.
- Describe your understanding of the concept essential medicines
 - What is essential medicines
 - Taking into account the WHO Framework of Provision for Pharmaceutical Services as depicted below



- What are the key processes involved in the provision of essential medicines in terms of

Component	Regional Hospitals	District Hospitals	Community Health Centre	Primary Health Clinic
Selection				
Procurement				
Distribution				
Use				
Legal Framework				
Management Support				

- Please explain if there is a documented framework for provisioning of essential medicines **for the district health services** in (i) South Africa or (ii) within your province.
- Does all component stated above follow the key processes mentioned
- How does your province approach the provision of essential medicines in general as well as specifically for the district health services ((i) Hospitals, (ii) Community Health Centres and (iii) Primary Health Clinics)?
- Has there been adequate provision of essential medicines for district health services ((i) Hospitals, (ii) Community Health Centres and (iii) Primary Health Clinics)? **if yes why or no why not.**

Level of Care	Narrative Content
Regional Hospitals	
District Hospitals	
Community Health Centre	
Primary Health Care	

- Should there be any special considerations for the provision of essential medicine for district health services ((i) Hospitals, (ii) Community Health Centres and (iii) Primary Health Clinics)? in terms of selection, procurement, use and distribution?
 - What special considerations?
 - Why do you think these special considerations are necessary?
 - What resources are required and why necessary
- What strategies should be or have been used to provide essential medicines for the district health services (Hospitals, Community Health Centres and Primary Health Clinics)?

Level of Care	Narrative Content
Regional Hospitals	
District Hospitals	
Community Health Centre	
Primary Health Care	

- What role should National Department of Health play in the provision of essential medicines for the District Health Services in South Africa?

SECTION D: DEBRIEFING AND CONCLUSION

- Do you have any other proposals for the framework for provision of essential medicines?

CONCLUSION

The draft report will be sent to you after analysis by the researcher for your review and comments before submission for examination.

I would like to thank you for your time and participation in this process.